Preventing psychosis: an interventionist-causal approach to psychological treatment development.



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Declaration

The work described in this thesis was carried out under the supervision of Professor Daniel Freeman and Professor Andrew Gumley. The work is entirely the candidate's own, with the exceptions listed below:

- The work undertaken in this thesis has been done in collaboration with people with lived experience of sleep disruption and psychotic experiences. A Lived Experience Advisory group comprising four people with relevant lived experience contributed to the design, conduct, and presentation of the findings. The advisory group are co-authors on the resulting publications.

- In line with the trial protocol, trial registration, and best practice guidelines the analysis of the randomised controlled clinical trial in Chapter 2 was carried out by independent blinded statisticians within the University of Oxford Primary Care Clinical Trials Unit: Dr Rebecca Seddon, Dr Nicola Williams, and Professor Ly-Mee Yu.

- In line with the peer methods approach, the qualitative data collection and analysis described in Chapter 3 were undertaken alongside peer researchers: Steven Evans, Abreen Rebello, and Tom Sharpe. The final analysis of the qualitative work was agreed by all members of the Lived Experience Advisory group.

I declare that the work presented has not been submitted for any other degree, in this or any other university or institute of learning.

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Finally, this thesis is dedicated to Bodhi – who gave me a whole new perspective on the importance of sleep. You bring the light – in every way.

Abstract

Background

Effective interventions are needed to prevent the occurrence of severe mental health problems, such as psychosis. Individually targeting causal psychological mechanisms provides a novel route for prevention in those at highest risk. One such contributory causal mechanism that is developmentally important, problematic in its own right, potentially tractable, and that young patients want treated is sleep disturbance.

Difficulties getting sufficient, high-quality sleep at the right time are prevalent in adolescence - the peak age of onset for serious mental health problems. Indeed, sleep disruption is common across many mental health problems. When sleep is disrupted there are noticeable effects on physical and mental health, including: reduced mood, energy, and activity, heightened anxiety, stress reactivity, and emotion dysregulation, and difficulties processing and recalling information. These are all plausible ways through which sleep difficulties may contribute to psychotic experiences.

When mental health difficulties are conceptualised as occurring within dynamic networks, highly connected problems become valuable treatment targets with the potential to bring a cascade of effects. As such, sleep disruption is a plausible target for preventing serious mental health problems. Interventionist-causal methods provide a framework to test both the treatment effect and the underlying theory regarding the putative causal factor.

The programme of research presented in this thesis focused on developing and evaluating a psychological intervention targeting a developmentally important, contributory causal factor - sleep disruption - in those at highest risk of psychosis. The objectives were to 1) establish the feasibility and acceptability of a randomised controlled trial to treat sleep problems in young people at ultra-high-risk of psychosis; 2) provide proof of concept of the clinical efficacy of the treatment on sleep disturbance, affective symptoms, and psychotic experiences, and 3) gain a first-person perspective on the experience of the treatment.

Method

Patient and public involvement was embedded throughout. Young people with relevant lived experience contributed to the design and conduct of the research. Applying an interventionist-causal approach a randomised controlled feasibility trial was conducted (Chapter 2). The SleepWell

trial involved patients aged 14 to 25 years who were at ultra-high-risk of psychosis and had sleep disturbance (ISRCTN85601537). Participants were randomised to receive either a novel, targeted, youth-focussed sleep intervention in addition to usual care or usual care alone. Assessor-blinded assessments were conducted at baseline, 3 months (post-intervention), and 9 months (follow-up). The eight-session psychological intervention targeted the key mechanisms which disrupt sleep: circadian rhythm irregularities, low sleep pressure, and hyperarousal. The treatment was specifically designed to deal with the unique aspects of sleep in youth, such as the changes in sleep architecture (e.g. delayed sleep-phase) and lifestyle factors (e.g. exam pressures, increasing independence).

In relation to objective 1, the key feasibility outcomes were the numbers of patients recruited and retained, treatment uptake, and data completion. Treatment acceptability was measured with the Abbreviated Acceptability Rating Profile (AARP). In relation to objective 2, the primary clinical outcome was insomnia at three and nine months assessed with the Insomnia Severity Index (ISI). The key secondary clinical outcomes were psychotic experiences and affective symptoms (depression and anxiety).

A peer methods qualitative evaluation (Chapter 3), co-facilitated with peer researchers with lived experience of psychotic experiences and sleep disruption, was used to gain an in-depth understanding of participants' views on the acceptability of the intervention and experience of trial participation (objective 3). Semi-structured interviews were conducted with 16 participants (n=10 intervention, n=6 control) and data were analysed using reflexive thematic analysis.

Results

Forty young people at ultra-high-risk of psychosis were recruited to the SleepWell randomised controlled clinical trial (mean age 16.9 years (SD=2.5, range 14-23 years) (Chapter 2). Twenty-one participants were randomly assigned to the SleepWell treatment and 19 to usual care alone. Twenty participants (95%) received a treatment dose. The median treatment acceptability score on the AARP was 48 (IQR 46 to 48; n=17; maximum possible score 48). All participants provided follow-up data. Compared to the usual care alone group, the SleepWell therapy group had large reductions in sleep disturbance (ISI adjusted mean difference = -8.12, 95% CI -11.60 to – 4.63; n=39; Cohen's *d* -2.67, 95% CI -3.81 to -1.52), which were sustained at 9 months (ISI adjusted mean difference = -5.83, 95% CI -9.31 to -2.35; n=39; Cohen's *d* -1.91, 95% CI -3.06 to -0.77). There were also reductions in depression, anxiety, and paranoia: depression ((Depression, Anxiety, Stress Scale (DASS)) adjusted mean difference = -4.00, CI -11.47 to 3.47; n=37; Cohen's *d* -0.35, CI-1.01 to

0.31), anxiety (DASS adjusted mean difference = -6.22, CI-12.60 to 0.16; n=37; Cohen's *d* -0.54, CI -1.09 to 0.01), and paranoia (Revised Green et al. Paranoid Thoughts Scale (RGPTS) Part-A adjusted mean difference = -4.70, CI-10.03 to 0.63; n=37; Cohen's *d* -0.52, -1.10 to 0.07; RGPTS Part-B adjusted mean difference = -4.51, CI-10.99 to -1.97; n=37; Cohen's *d* -0.38, -0.93 to 0.17). These changes were sustained at the 9-month follow-up. Although small-to-medium effect sizes were observed on the Comprehensive Assessment of At-Risk Mental States (CAARMS), the confidence intervals at both timepoints were wide and covered a range from potentially increasing to decreasing scores.

In the peer-methods qualitative study (Chapter 3), four themes were generated from the accounts: 1) The challenge to access mental health treatment ('Bouncing between services'); 2) Sleep problems and mental health difficulties are intertwined ('An obvious link'); 3) Flexibility in therapy provision matters ('Tailored to me as a person'; 4) Improving sleep leads to wider benefits ('Fixing the sleep helped everything else'). Participants described a frustrating journey to access mental health treatment, marked by rejection and invalidation, which resulted in hopelessness and often resignation. The interaction between sleep disruption and other mental health difficulties was seen as obvious. Treatment for sleep problems was highly valued. The clear focus, therapeutic style, and flexible delivery of the treatment created patient ownership, active engagement, and hope. Participants described transformative changes: better sleep, fewer voices and fears, and improved mood and confidence. Improving sleep made a difference to everyday life. Routes to improve the treatment were highlighted.

Conclusions

Sleep disruption is a meaningful treatment target for young people at ultra-high-risk of psychosis. Treating sleep problems likely leads to a wide range of improvements in mental health, including reducing psychotic experiences. This interventionist-causal method efficiently demonstrates the potential clinical benefits of the treatment and supports the premise of sleep disruption as a contributory causal factor in the occurrence of psychosis. This is the first time this targeted mechanistic approach has been applied to a single causal factor in the development of psychological treatments to prevent the emergence of severe mental health problems, including psychosis, in young people. The method could be applied in future research to address other psychological contributory causal factors. The primary limitation of this work is that it was not designed or powered to detect clinical effects definitively. Nor did the trial test how the sleep

treatment affected the psychotic and emotional symptoms. A larger trial, with embedded mediation and moderation, is needed to assess the clinical benefits indicated in this feasibility study.

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Chapter One

A causal interventionist approach to preventing psychosis: An introduction[1]

Identification of those at highest risk of psychosis provides an opportunity for preventative intervention. For the last 30 years, efforts have been made to identify this ultra-high-risk group and to develop effective interventions to delay or prevent the onset of psychosis (Yung et al., 2005). This has resulted in the provision of specialist services (e.g. NHS England, 2016; NICE 2014) and there have been observed reductions in overall transition rates (Formica et al., 2022). Yet the clinical picture is complex. This group of young people are also at increased risk of other mental health problems, such as depression, and often experience poor long-term outcomes (Lin et al., 2015; Polari et al., 2018). Although these young people often seek help, current treatment effects are small (Davies et al., 2018; Yung, 2017). New approaches are needed.

From a network perspective, mental health problems are understood to arise from the causal interplay (both direct and reciprocal) between different symptoms (Borsboom & Cramer, 2013). Therefore, targeting one specific symptom will have an impact on other causally connected problems, such as low mood, anxiety, and psychotic experiences. Interventionist-causal methods provide an experimental manipulation technique to test the effect of individually targeting a putative causal factor through a treatment (Kendler & Campbell, 2009; Freeman, 2011). This gives a route to both determine the effects of the treatment and test the underlying theory.

The approach taken in this thesis is to focus on identifying and targeting causal mechanisms that are developmentally important, problematic in their own right, and that young people want treated. One such factor is sleep disruption. Sleep problems are common in young people at clinical high-risk, they are a contributory causal factor in the occurrence of psychotic experiences, and they are

[1] *This section has been adapted from the following papers, attached in Appendix 1.1 and 1.2:*

Waite F, Kabir T, Johns L, Mollison J, Tsiachristas A, Petit A, et al. (2020). Treating sleep problems in young people at ultra-high-risk of psychosis: Study protocol for a single-blind parallel group randomised controlled feasibility trial (SleepWell). BMJ Open, 10:e045235. https://doi.org/10.1136/bmjopen-2020-045235.

Waite F, Sheaves B, Isham L, Reeve S, & Freeman D. (2020). Sleep and schizophrenia: From epiphenomenon to treatable causal target. Schizophrenia Research. 221:44-56. doi: 10.1016/j.schres.2019.11.014

potentially tractable (Waite, Sheaves, et al., 2020). The aim of the work reported in this thesis is to test the feasibility, acceptability, and initial clinical efficacy of a psychological intervention to treat sleep problems and reduce psychotic experiences in young people at ultra-high-risk of psychosis.

1.1 The need for targeted prevention

1.1.1 Learning from first-person accounts

"I was just getting worse and worse, hearing noise. I just had enough … just cant take it."

(patient quote, Hardy et al 2009).

In mental health services there is a specific group of young people identified as being at ultra-high-risk of psychosis. First person accounts from this group of young patients highlight the clinical complexity and level of need. Young patients describe unusual and frightening experiences (Brew et al 2017), the sense that 'something was wrong with them' (Uttinger et al., 2018), disruption to daily life (Byrne & Morrison, 2010; Cotter et al., 2019), and concerns of an uncertain future (Hardy et al., 2009). In an extensive review led by experts by experience, including people with lived experience of psychosis and family members and carers, conducted in collaboration with academics, first person accounts from numerous sources were assessed and the findings synthesised (Fusar-Poli et al., 2022). Network maps were used to present the themes at four different stages of psychosis. In those at high risk, termed in the review as the 'prodromal phase', patients described a wide range of difficulties (figure 1).

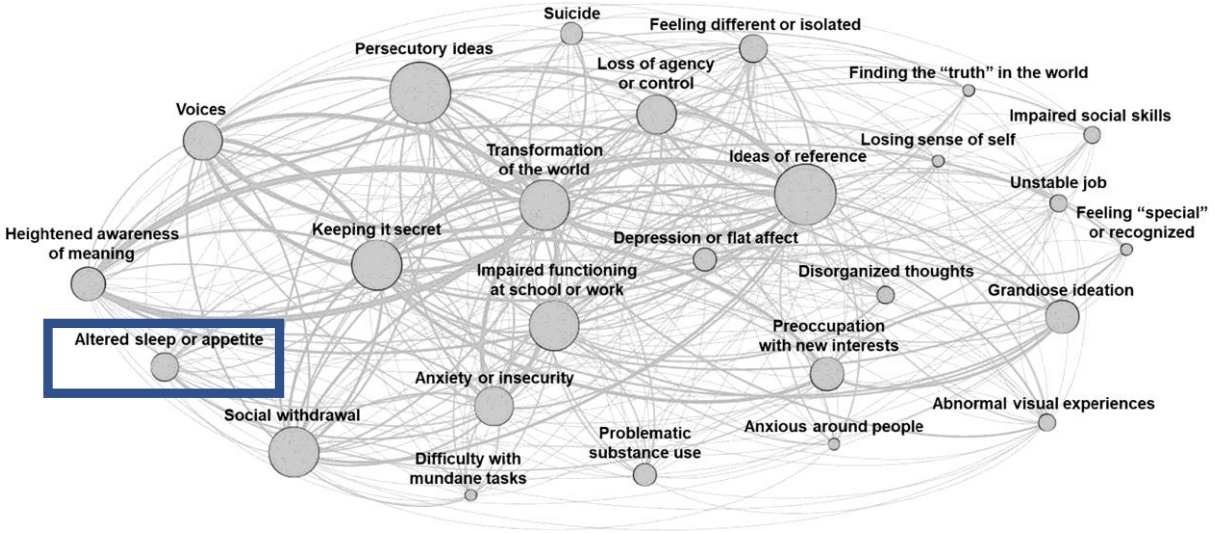

Figure 1.1. Network map of lived experiences of psychosis during the prodromal stage. The nodes represent the experiential themes, and the edges represent the connections between them. The size of each node

reflects the number of first-person accounts addressing that experiential theme. The thickness of the edges reflects the number of connections between the themes. (Fusar-Poli et al., 2022). Box added by thesis author.

The accounts were characterised by the sense of being on the cusp of something important, that everyday experiences held increased salience, and a loss of sense of self. This caused confusion and fear. There is a clear tension: young patients are eager for help (Byrne & Morrison, 2014) yet they sense they have something to hide, a need to keep these frightening experiences secret (Fusar-Poli et al., 2022). This highlights the importance of finding accessible, low stigma, and engaging interventions. Collaborating with people with lived experience of psychotic experiences and sleep disturbance, as colleagues (peer-researchers) and advisors, is essential to achieve the development of such interventions.

1.1.2 A complex clinical picture and poor long-term trajectories

It is clear in the first-person accounts that young patients face multiple, co-occurring problems: a complex clinical picture. Indeed, there is diagnostic uncertainty both in the immediate presentation and in terms of trajectory – there are multiple different diagnostic outcomes for young patients (Polari et al., 2018). The key markers of being at ultra-high-risk are the presence of sub-threshold psychotic symptoms (attenuated psychotic experiences), brief intermittent psychotic symptoms (BLIP), or the pairing of family risk with a decline in functioning and attenuated experiences (Yung & McGorry, 1996a). Many young patients have experienced childhood trauma (Kraan et al., 2015). There are also high rates of comorbidity: with only 21% of young patients at high risk not meeting diagnostic criteria for another mental health problem (Addington et al., 2017). These co-occurring problems are often a key reason given for help-seeking (Falkenberg et al., 2015) and predict poor long term trajectories (Schirmbeck et al., 2022). Patients experience deterioration in functioning and reduced quality of life (Fusar-Poli et al., 2015). In qualitative accounts patients describe difficulties with interpersonal relationships and time use, and a desire to live a 'normal life' (Cotter et al., 2019). Everyday life becomes challenging. Yet there is also uncertainty regarding the longer-term clinical trajectory.

Rates of transition to psychosis in this high-risk group are approximately 20% within 2 years (Fusar-Poli et al., 2016). Disruption to functioning is a key predictor of transition (Bonnett et al., 2025; Polari 2021). However, within the ultra-high-risk group there is considerable heterogeneity (note the three distinct subcategories outlined above: family risk, BLIP, and attenuated psychotic experiences). Indeed each subcategory carries a different risk profile for transition to psychosis (Fusar-Poli et al., 2016). Further to this, attenuated psychotic experiences are a marker of potential

risk for a number of different serious mental health problems, including personality and mood disorders (Fusar-Poli et al., 2013). Even for young people at ultra-high-risk who do not go on to meet diagnostic criteria for psychosis (or other serious mental health problems) the long-term outcomes can remain poor (Addington et al., 2019; Carrión et al., 2013; Lin et al., 2015). There are multiple different clinical trajectories in the high-risk group (figure 2), with only a minority showing sustained improvement (Polari et al., 2018). This is particularly important given the key developmental period in which the onset of severe mental health problems typically occurs.

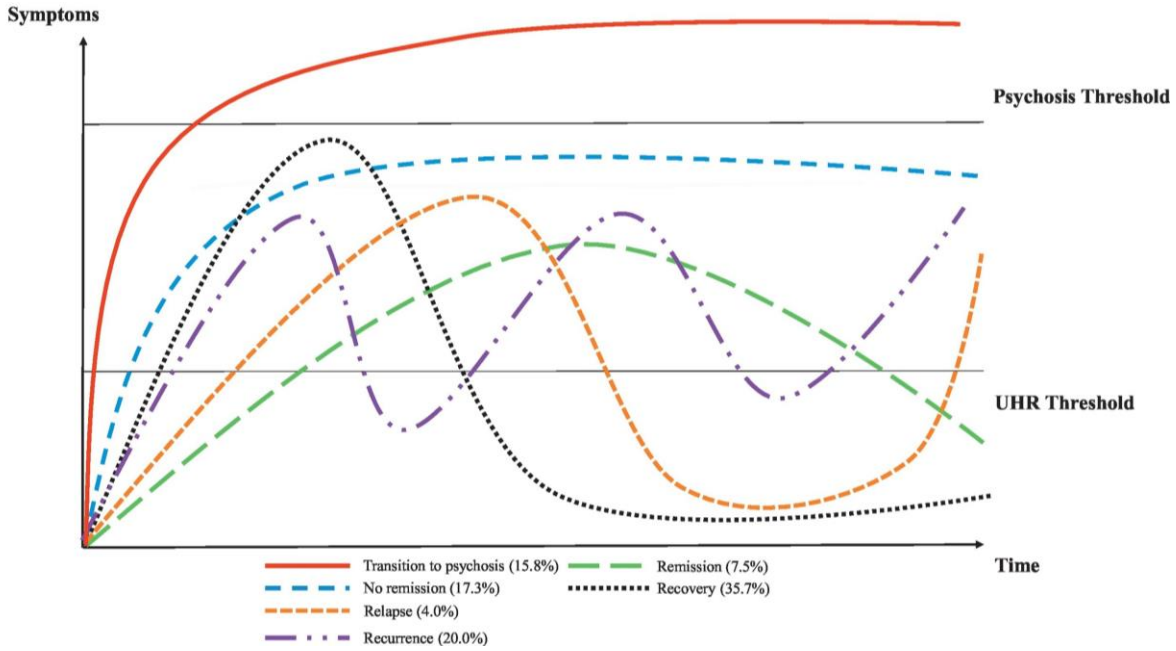

Figure 1.2. Clinical trajectories in young people at ultra-high-risk of psychosis (Polari et al., 2018)

1.1.3 The developmental context: timing matters

The peak age of onset for mental health problems, including psychosis, is between the ages of 14 and 25 years (McGrath et al., 2023; Solmi et al., 2022) – see figure 3. Three quarters of all lifetime instances of mental health disorders have started by the age of 24 (Kessler et al., 2005). Suicide is one of the leading causes of death in this age group (Office for National Statistics, 2020; World Health Organisation, 2024). Yet this is a key developmental period for establishing independence, forming relationships, and finishing education or starting employment (Blakemore, 2018). Indeed, those not in employment, education, or training at this age experience detrimental effects on physical and mental health across the life course (Office for National Statistics, 2024; Public Health

England & UCL Institute of Health Equity, 2014). As such it is a critical period for preventative intervention.

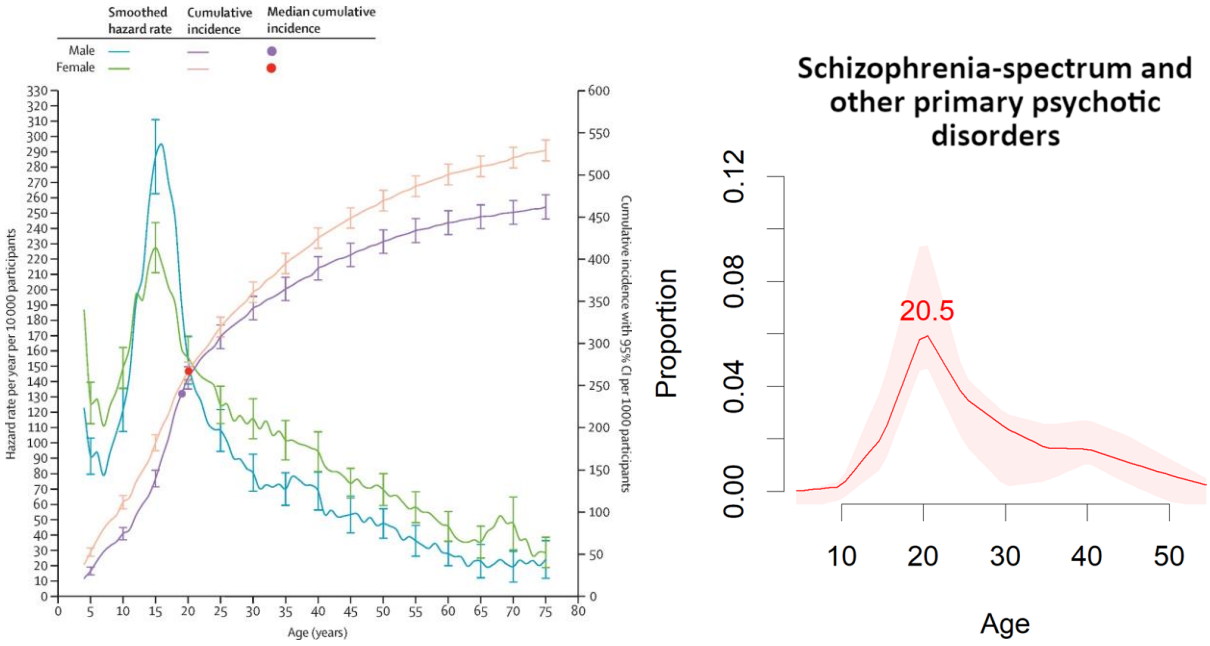

Figure 1.3. A) Age of onset and cumulative risk of onset of mental health disorders (McGrath et al 2022); B) Meta-analytic distribution of age of onset for schizophrenia-spectrum and primary psychotic disorders (Solmi et al, 2022).

1.1.4 Models of prevention

Preventative healthcare approaches can occur at several levels of intervention – see figure 4. Universal prevention is a population-level approach, aiming to reduce exposure to risk factors or increase exposure to protective factors. Examples of universal prevention interventions include education and awareness campaigns and school-based programs. One suggestion currently advocated for is a public health campaign to inform young people of the association between early and persistent use of high potency cannabis and the onset of psychosis (Murray et al., 2022). Targeted approaches include selective prevention in subgroups with specific risk (e.g. children of parents with psychosis; see Sommer et al., 2016 for an example intervention). Selective prevention approaches may be important given the elevated rates of onset in minoritised groups (Chui et al., 2021; Coelho et al., 2022; Morgan et al., 2017). Indeed, it is argued that these preventative approaches better account for the social, political, cultural, and economic context in which mental health problems occur (Anglin et al., 2020). Indicated approaches work with people who experience attenuated symptoms of the target problem – in the field of psychosis prevention this group of young people are described as being at ultra-high-risk.

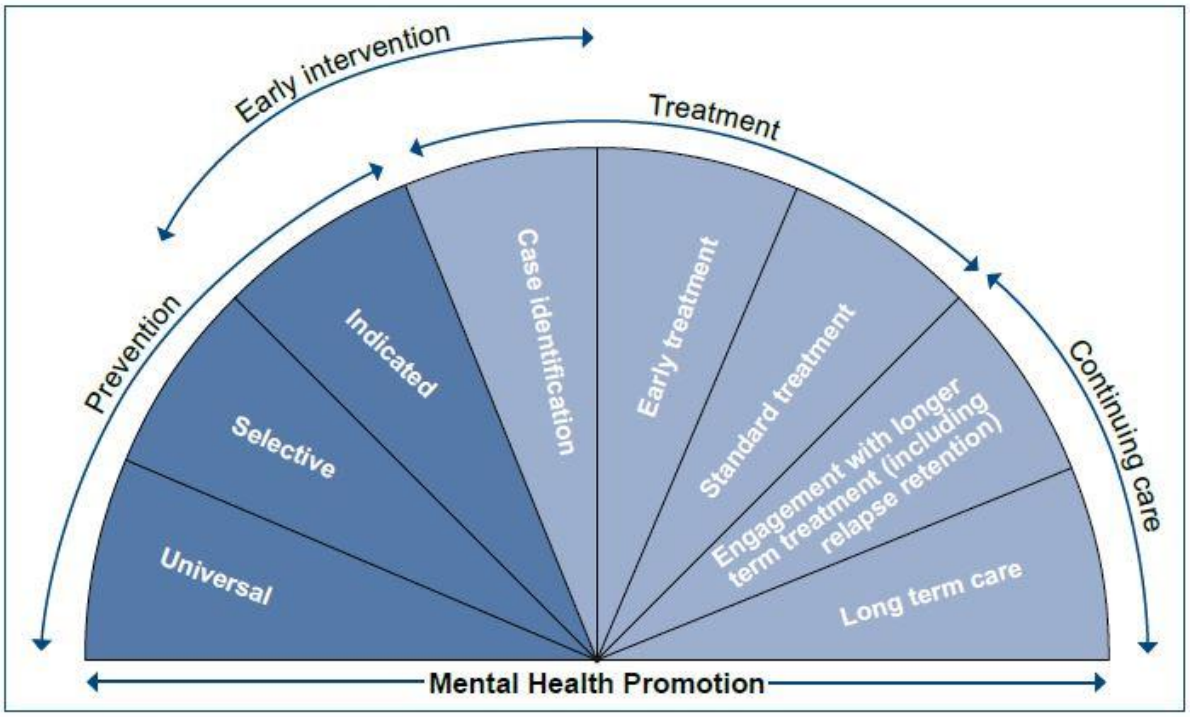

Figure 1.4. Model of the spectrum of interventions for mental health problems and mental disorders (Mrazek and Haggerty, 1994).

1.1.5 Identifying those at highest-risk: the ultra-high-risk paradigm

The key diagnostic marker for identifying young people at ultra-high-risk of psychosis is the presence of attenuated (sub-threshold frequency or intensity) psychotic experiences (Yung et al., 2005). This could include suspiciousness, which goes beyond cultural norms and arises without logical evidence, often causing distress and impairment, but is not held with certainty, or for which the individual can generate doubt. Or perceptual anomalies such as hearing a sound in the absence of external stimulus. This could include sounds such as a phone ringing, name being called, or a whispering, murmuring, or vivid but infrequent voice. Further to this, a decline in functioning, a desire for help, and a typical age range (14-30 years) are additional criteria for identification (Yung & Nelson, 2013). These criteria seek to provide a reliable framework for identifying those at ultra-high-risk, yet there is recognition the distinction between high risk and psychosis is somewhat arbitrary (van der Gaag et al., 2019) – this is discussed further below. There are a number of assessment tools for identifying those at ultra-high-risk, with efforts underway to harmonise practice (Woods et al., 2023). In the National Health Service (NHS), and the approach employed in this thesis, identification of those at ultra-high-risk is via the Comprehensive Assessment of At-Risk Mental States (CAARMS; Yung et al., 2005) which informs the criteria outlined above.

However, other frameworks for conceptualising and identifying high-risk individuals exist, such as the Basic Symptoms approach (Schultze-Lutter et al., 2007). The Basic Symptoms approach can facilitate even earlier detection of subtle subclinical changes in thinking, perception, and affect, and may be considered a complementary approach to the ultra-high-risk paradigm. Identification of Basic Symptoms has been operationalised using validated measures for example the Bonn Scale for the Assessment of Basic Symptoms (BSABS; (Klosterkötter et al., 1996).

The ultra-high-risk concept is underpinned by a specific theoretical position regarding psychosis (see Yung et al., 1996; Yung 2017). Most notably that psychosis (and particular psychotic experiences) exists on a dimensional continuum of severity in the population (e.g. Bebbington et al., 2013; Bird et al., 2019), rather than being discontinuous or qualitatively distinct from 'normal' experiences. Traditionally this was held as a key division between psychoses and neuroses, including anxiety and depression, which could be understood or categorised as a variation from the norm. The understanding that psychotic experiences, and therefore psychosis as a diagnosis, exists on a continuum raises the assumption that "defining the onset of disorder involves a degree of judgment [sic]" (Yung et al., 1996; p.286). The question then becomes how to define onset. Is this marked by severity and distress caused by a single psychotic experience, or a combination of less severe symptoms?

From a categorical perspective the covariation of psychotic experiences is understood to reflect an underlying common cause: the psychotic disorder itself. However, psychotic experiences such as paranoia, hallucinations, and grandiosity are not only phenomenologically distinct – as shown in factor analytic studies as well as stated clearly in first person accounts (Peralta & Cuesta, 1999; Zavos et al., 2014) - but that they can also occur independently (Hermans et al., 2020) and carry a degree of aetiological distinction (Zavos et al., 2014). In contrast, from a network perspective (see section 1.2.1) the covariation of psychotic experiences is understood to arise from the causal interplay (both direct and reciprocal) between symptoms (Borsboom & Cramer, 2013). As such psychotic experiences are conceptualised to be both distinct and inter-related. Further consideration is also needed to the conceptualisation of psychotic experiences themselves – which are multidimensional and vary in degree of preoccupation, intensity, frequency, and associated affect. The nuance of defining, identifying, and understanding the clinical presentation for this group is fundamental to developing effective treatments and interpreting the evidence base to date.

1.1.6 The potential of intervening early

There have now been over 25 randomised controlled trials evaluating interventions in the ultra-high-risk group, including more than eight trials of Cognitive Behavioural Therapy (CBT). There has been a range of treatment targets and approaches including both pharmacological (such as omega-3, cannabidiol, and antipsychotic medication) and psychological (including CBT, family therapy, and cognitive remediation therapy). The first trials of CBT for young patients at ultra-high-risk of psychosis demonstrated the potential value of this approach (Morrison et al., 2004, 2011; van der Gaag et al., 2012), with benefits observed at four-years post intervention (Ising et al., 2016). Indeed, there was evidence to suggest there may be additional benefit of an enriched CBT protocol including active engagement in homework tasks and understanding cognitive biases (van der Gaag et al., 2012). The CBT interventions were highly valued by patients. Qualitative accounts highlight three core components: firstly, that the therapy provided a chance to talk – which focused on interpersonal engagement, informality and normalisation, and opening up; secondly that monitoring provided clarity and reassurance and that the therapeutic process helped navigate challenges; and finally, that rethinking things was hard work but allowed individuals to move forward (Byrne & Morrison, 2014). These approaches were also cost effective (Ising et al., 2015). And a recent review concluded that the approaches may even be cost saving (Ologundudu et al., 2021).

As a result, preventative interventions are included in several national and international clinical guidelines (e.g. National Institute of Health and Care Excellence (NICE) 2014; Schmidt et al., 2015). The NICE guidelines identify those at high-risk using the following criteria: experiencing distress and a decline in functioning, accompanied by: transient or attenuated psychotic symptoms or other experiences indicative of possible psychosis or have a first degree relative with psychosis. For those identified as potentially at high-risk the guidelines recommend a specialist assessment followed by psychological treatment (CBT delivered individually over at least 16 sessions, with or without family therapy) accompanied by treatments for other presenting difficulties (including anxiety, depression, emotion regulation difficulties, and substance use). The guidelines prohibit the use of antipsychotic medication in this group. To support delivery of the clinical recommendations there has been an effort to increase service provision within England (NHS England, 2016). It has been suggested that improvements in services may account for observed reductions in overall transition rates (Formica et al., 2022). However, the clinical reality faced by many young people in the high-risk group is that is remains hard to access timely and effective treatment.

Despite the clinical guidelines and service mandates there remains debate in the literature regarding the potential benefits of interventions in the high-risk group and which types of intervention (pharmacological or psychological) hold greatest promise. For example, Davies and colleagues argue that there is no evidence that any specific intervention is particularly effective over others in preventing psychosis, nor in the acceptability of the treatment (Davies et al., 2018). In contrast Mei and colleagues conclude that the evidence supports the premise that psychological interventions, particularly CBT is effective in reducing transition, and potentially brings small effect size reductions in attenuated symptoms (figure 5) (Mei et al., 2021).

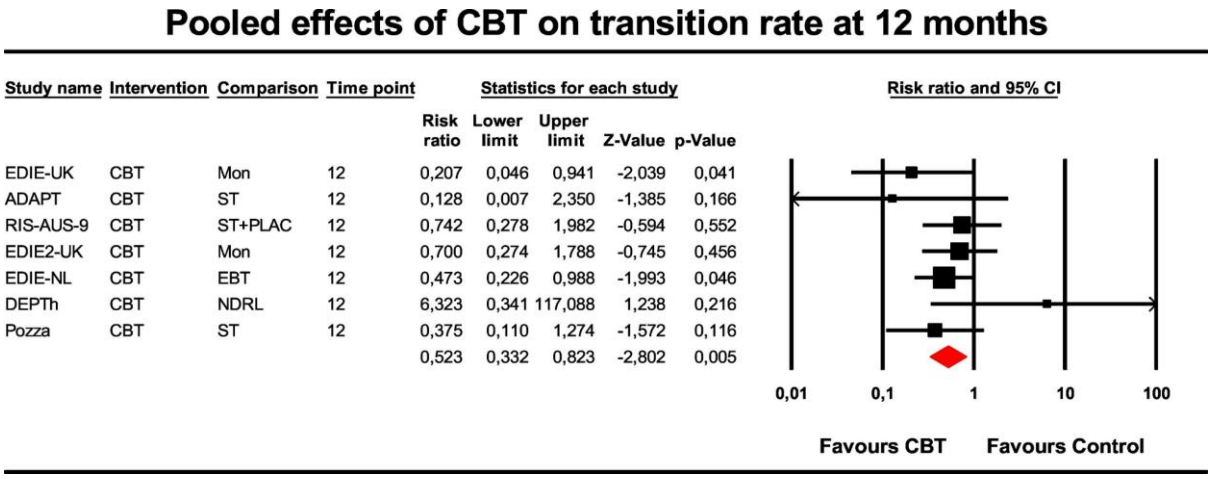

Figure 1.5. The pooled risk ratio of CBT versus any control on risk of transition to psychosis at 12 months follow up (Mei et al., 2021). *CBT = Cognitive behavioral therapy; Mon = Monitoring; ST = Supportive therapy; PLAC=Placebo; EBT = Evidence-based therapy for help-seeking disorder; NDRL = Non-directive Reflective Listening.*

For children and adolescents specifically, a recent meta-analysis concluded that preventative interventions result in small to moderate effect size improvements in attenuated positive, negative, and total symptoms, as well as improved functioning (Frearson et al., 2025). But insufficient evidence was found for reducing transition to psychosis or ameliorating depression. Once again in contrast, the most recently published meta-analysis concluded that there is no evidence that any interventions have a sustained effect on transition or any other outcomes (Minichino et al., 2025). The one consistency between reviews is that any effects reported are small.

The debate may in part be due to tensions in the underlying theoretical assumptions applied in this field (as well as the assumptions regarding non-inferiority in network meta-analyses; Mei et al 2021). For example, from the earliest work in this field, the aim of preventative intervention was twofold: to manage current symptoms and problems, and to reduce the risk of developing a psychotic disorder (Yung et al., 1996). However, trials have typically focused on transition as the primary outcome without giving the current problems equal focus (Yung, 2017). This means there is a range in treatment focus and mixed reporting on outcomes related to current symptoms and functioning. Not only does this make it challenging to compare the potential benefits of different treatments, but it also means trials are typically underpowered to sufficiently test the binary outcome of transition (expected in only 20% of the participants over the coming 24 months) and may miss the meaningful clinical outcomes for those who do not transition. Further to this, it does not account for the theoretical understanding of psychotic experiences occurring on a continuum, multifactorial causation – meaning there are distinct yet inter-related difficulties, or the diagnostic uncertainty and range of potentially detrimental trajectories young people at ultra-high-risk face. Taking a mechanistic focus, built on phenomenological accounts from people with lived experience and an understanding of multifactorial causation, gives a route to simultaneously assess a number of clinically meaningful outcomes. This may be a direction to improve treatment outcomes (van der Gaag et al., 2019).

1.2 A causal-interventionist approach

1.2.1 A network perspective

Although psychotic experiences such as paranoia, hallucinations, grandiosity, and cognitive disorganisation are distinct and can occur independently (Hermans et al., 2020; Zavos et al., 2014), they often co-occur. This challenges the idea of them being merely interchangeable markers of an underlying disorder. Network theory posits that these symptoms actively interact with each other, with the potential to create self-sustaining loops (Borsboom & Cramer, 2013). This may be particularly important for those with emerging difficulties which are typically characterised by a heterogeneous mix of symptoms that interact and fluctuate along unpredictable paths over time (McGorry & Nelson, 2016). These are associated with distress, impairment, and, thus, a need for care (Shah et al., 2020). These reflections have driven the development of a clinical staging model, which recognises the evolution of clinical presentations over time without assuming linearity of relationships between different problems (McGorry et al., 2014) When conceptualised within these dynamic networks, highly connected problems become valuable treatment targets with the

potential to bring a cascade of effects. Indeed many risk factors for psychosis have shared causal mechanisms (Oliver et al., 2024). Therefore, targeting one specific symptom will have an impact on other causally connected problems, such as low mood, anxiety, and psychotic experiences.

1.2.2 Interventionist-causal tests

Testing this mechanistic hypothesis requires manipulation methods. There are two main paradigms for establishing causal evidence: brief experimental tests which manipulate the mechanism and measure the immediate change in the target outcome or interventionist-causal randomised controlled trials of treatments focused on a mechanism and measuring change in the primary clinical outcome (Kendler & Campbell, 2009). As such, interventionist-causal methods provide a framework to test both the treatment effect(s) and the underlying theory regarding the putative causal factor. This approach can be further tightened: by focusing on one single causal factor at a time to give even greater confidence in the learning (Freeman, 2011). Mediation tests, which assess the direct and indirect effects between variables, can strengthen the conclusions drawn from causal tests (Dunn et al., 2015). However, caution should remain as confounds and variables not measured or tested in the model may still be fundamental to understanding a causal chain.

1.2.3 Multifactorial causation

Within these dynamic networks it is proposed that causation is multi-factorial. In essence, that there is no single cause nor that a single treatment target will suffice. Therefore, a range of potential treatment targets can be identified. If effective, these could become treatment options enabling personalisation and patient choice. This targeted, mechanistic approach was successfully applied in the treatment of persecutory delusions in patients with psychosis (Freeman, Emsley, et al., 2021). Yet this approach has not been applied in young people at ultra-high-risk. The mechanisms considered for the work in this thesis were those that are developmentally important, plausible contributory factors, that young patients want treated, and are potentially tractable. Selecting and targeting a single factor for manipulation (or putative causal mechanism for treatment) enables testing of the treatment effect on the mechanism itself, on psychotic experiences (if causally related), and by measuring other putative factors it gives a chance to learn if the mechanism leads to change in other factors. The factor targeted in the work reported in this thesis is sleep disruption.

1.3 One putative contributory causal factor: sleep disruption

"*I would just sleep through the day and that put a massive strain on my social life, mood, and mental health. It turned my life the other way around, I would be up at night and then I wouldn't be up in the day, wouldn't go out and see people because I was sleeping, I think it was very unhealthy.*"

(Patient quote, Waite et al., 2018).

1.3.1 Recognising the importance of sleep disruption: a paradigm shift

Since the first descriptions of psychosis sleep dysfunction has been a feature of patient, family, and clinician accounts (see Kraeplin, 1919; Birchwood et al., 1989; Yung & McGorry, 1996b). Despite this, sleep problems have been overlooked as a treatment target. Historically, sleep disruption has been seen as a non-specific epiphenomenon or secondary consequence of a core psychotic disturbance. Recently there has been increasing interest in a different view: that sleep dysfunction may be a potential causal mechanism in the onset and persistence of psychotic experiences (Freeman et al., 2009; Reeve et al., 2015). This paradigm shift identifies sleep disruption as a potential novel treatment target for psychotic symptoms. It also provides a route to determine causality: if successful treatment of sleep problems results in improvements in psychotic experiences, then a causal relationship is demonstrated.

Sleep problems are common in adolescence and emerging adulthood– the peak age of onset for mental health problems (McGrath et al., 2023; Solmi et al., 2022). In young people, sleep disruption is associated with poor physical and mental health and worse social outcomes, including greater suicide risk, obesity, and lower educational attainment (Blake et al., 2017; Carney et al., 2018). When sleep is disrupted, there are noticeable effects: low mood and energy, inactivity, heightened anxiety, stress reactivity, and emotion dysregulation, and difficulties with information processing and memory. These are all plausible mechanistic routes through which sleep difficulties may contribute to psychotic experiences.

In a systematic review that included 58 papers, sleep disruption was found to predict the onset and persistence of psychotic experiences such as paranoia and hallucinations, with negative affect identified as a partial mediator of this relationship (Waite, Sheaves, et al., 2020). (The findings of this review have been replicated in recent reviews focused specifically on the high-risk group (e.g. Bagautdinova et al., 2023; Clarke et al., 2021; Dondé et al., 2022)). The review included qualitative accounts, in which patients recognised the detrimental effects of disrupted sleep and were keen

for treatment. Further to this, initial evaluations of psychological interventions addressing sleep problems in patients with psychosis report large effect size improvements in sleep and this may be accompanied by modest resultant improvements in psychotic experiences (Waite et al., 2020). It should be noted that to date the trials with patients with psychosis have generally been small, limiting the ability to determine the effect of improving sleep on psychotic experiences. Yet taken together an initial clinical picture forms: sleep disturbance is a common and treatable problem across the spectrum of psychosis severity which is important to treat in its own right and may also lessen psychotic experiences, with the potential for preventing psychosis in those at highest-risk.

1.3.2 Sleep disruption as a causal contributory factor to psychotic experiences

Sleep problems are common both in patients with persistent psychosis (Bagautdinova et al., 2023; Freeman et al., 2019) and in young people at ultra-high-risk of psychosis (Clarke et al., 2021; Poe et al., 2017; Zanini et al., 2015), with estimates of prevalence in the at-risk group of up to 75%. The range of sleep problems in patients with early psychosis is wide (Dondé et al., 2022). There are also high rates of comorbidity (Reeve, Sheaves, et al., 2019). In qualitative accounts, patients describe disrupted sleep timing, anxious waking in the night due to nightmares or unusual experiences, and the negative impact on daytime functioning (Waite et al., 2018). Insomnia and circadian rhythm disruption are associated with the severity of psychotic experiences and poor outcomes (Clarke et al., 2021; Formica et al., 2024; Goines et al., 2019; Lunsford-Avery et al., 2017; Reeve, Nickless, et al., 2019; Stowkowy et al., 2020). Findings from a large European prospective multicentre study indicate that sleep problems are highly predictive of transition to psychosis (Ruhrmann et al., 2010).

Longitudinal (Zaks et al., 2022), experimental (Reeve, Emsley, et al., 2018), and interventionist (Freeman, Waite, et al., 2015; Freeman et al., 2017) studies have identified sleep disturbance as a putative contributory causal factor in the occurrence of psychotic experiences, including paranoia and hallucinations (Clarke et al., 2021; Freeman et al., 2020; Waite et al., 2020). Negative affect is implicated as a key route by which insomnia may influence psychotic experiences (e.g. Bagrowska et al., 2022; Ballesio et al., 2022; Kasanova et al., 2020; Freeman et al., 2009). Indeed, when sleep is deliberately reduced, in experimental manipulation studies, it results in an increase in psychotic experiences (Reeve, Emsley, et al., 2018). These increases in psychotic experiences due to worsening of sleep were mediated by increases in negative affect and related processes (such as worry and negative self-views) (Reeve, Emsley, et al., 2018). Conversely, successfully treating sleep problems leads to an improvement in psychotic experiences. A large randomised controlled trial

with 3755 university students found that psychological treatment was highly effective for treating insomnia and led to significant improvements in non-clinical hallucinations and paranoia (Freeman et al., 2017). Sleep treatment in this trial also reduced the likelihood that students reached the threshold for being at ultra-high-risk of psychosis.

Sleep disturbance is also a contributory factor across a wide range of other mental health problems, including anxiety, depression, and bipolar disorder (Freeman, Sheaves, et al., 2020; Hickie et al., 2013). Therefore, treating sleep problems may also prevent other mental health problems, such as depression and anxiety, and promote improvements in functioning and physical health (Scott et al., 2021). In those at highest risk of a mental health condition, treating sleep problems may be a plausible preventative strategy. However, to successfully tackle sleep disturbance in this group, treatment needs to address the complexity of sleep presentations via techniques to improve sleep pressure, align circadian timing, and reduce hyperarousal (Freeman & Waite, 2025). Patients are eager for help (Waite et al., 2018). Yet few have received any treatment (Rehman et al., 2017; Stafford et al., 2024).

1.3.3 The potential for intervention

Cognitive Behavioural Therapy for insomnia (CBTi) is the first-line treatment for adults with insomnia (e.g. NICE, 2022; Qaseem et al., 2016) and has been effectively adapted (and extended for example to include nightmares and hypersomnia) for people with psychosis (Waite, Myers, et al., 2016; Waite, Sheaves, et al., 2020; Waite & Sheaves, 2020; Waters et al., 2017; Freeman & Waite, 2025), including patients with persistent psychotic experiences (Freeman, Waite, et al., 2015), patients on an acute inpatient ward (Sheaves, Freeman, et al., 2018; Sheaves, Isham, et al., 2018), and for the treatment of nightmares in patients with persecutory delusions (Sheaves et al., 2019). Not only does CBTi lead to large improvements in insomnia – for example in a meta-analysis of 87 trials of CBTi, in people without psychosis, the pooled effect size was large (Hedge's g=0·98) (van Straten et al., 2018), with similar large effects seen in adolescents (Blake et al., 2017) – but there are also significant effects on depression and anxiety (Freeman, Waite, et al., 2015; Freeman et al., 2017; Henry et al., 2021), and smaller effects on psychotic experiences (Freeman, Waite, et al., 2015; Freeman et al., 2017). It is likely the treatment effects on psychotic experiences are mediated by improvements in depression and anxiety (Freeman et al., 2017; Henry et al., 2021).

Building on the principles of CBTi and the work treating sleep difficulties in adults with psychosis, a brief youth-focused psychological intervention to address sleep problems in young people at

ultra-high-risk of psychosis (SleepWell) was developed (Waite et al, 2018; Bradley et al., 2018). The core treatment techniques included stimulus control, circadian realignment, and regulating daytime activity. In an uncontrolled case series with 12 young people at ultra-high-risk of psychosis, outcome assessments were conducted pre-treatment, post-treatment, and at a one-month follow-up. Following the intervention, there were improvements in sleep, affective symptoms, and psychotic experiences, and the changes were maintained at the 1-month follow-up. Throughout the 10-week study period, no participants transitioned to psychosis. The treatment was popular (for example, 89% attendance rate) and patients were keen to participate. In qualitative interviews, participants described achieving meaningful change in both sleep and well-being by developing a 'repertoire of skills' (Waite et al., 2018). The treatment now requires testing in a randomised trial to determine the preliminary clinical effects on psychotic experiences and the potential to prevent the onset of psychosis.

1.4 Aims of the thesis work

Effective prevention of severe mental health issues, including psychosis, requires innovative approaches. One potential strategy is to target individual psychological causal mechanisms in those at highest risk. Sleep disturbance is a prime example—it is developmentally significant, inherently problematic, potentially treatable, and a priority for young patients. Conceptualising mental health issues within dynamic networks highlights that highly interconnected problems can serve as valuable treatment targets, potentially triggering a cascade of positive changes. In this context, sleep disruption emerges as a promising target for preventing severe mental health problems. Interventionist-causal methods offer a framework for testing both the clinical effects of treatment and the underlying theory of causation.

In this thesis a programme of research is reported that focused on developing and evaluating a psychological intervention for sleep disruption in young people at ultra-high-risk of psychosis. It took forward the SleepWell work in preparation for a future definitive trial. The objectives were to: 1) establish the feasibility and acceptability of a randomised controlled trial to treat sleep problems in young people at ultra-high-risk of psychosis (Chapter 2); 2) provide initial proof of concept for the treatment's potential efficacy on sleep disturbance, affective symptoms, and psychotic experiences (Chapter 2); and 3) capture first-person accounts of the treatment and trial participation experience drawing on peer research methods (Chapter 3).

Chapter Two

A targeted psychological treatment for sleep problems in young people at ultra-high-risk of psychosis: the SleepWell feasibility randomised controlled trial[2]

2. 1. Introduction

The presence of attenuated psychotic symptoms alongside disruption to everyday life are key criteria used to identify young people at ultra-high-risk of psychosis. This group of young people are at elevated risk of psychosis as well as other mental health problems such as depression, and often experience poor long-term outcomes (Polari et al., 2018). Despite seeking help, current treatment effects are limited (Davies et al., 2018; Yung, 2017). New approaches are needed (see Chapter 1). As described in Chapter 1, the approach taken in this thesis is on identifying and targeting individual psychological causal mechanisms that are developmentally important, problematic in their own right, and that young people want treated. Sleep disruption is one such issue. In this chapter, the first randomised controlled trial (RCT) investigating the feasibility and preliminary clinical outcomes of treating sleep problems in young people at ultra-high risk of psychosis is reported.

2.1.1 Sleep problems: common, complex, and potentially causal

Sleep problems are widespread in young people at ultra-high risk of psychosis, with estimates of prevalence exceeding 75% (Bagautdinova et al., 2023; Clarke et al., 2021; Poe et al., 2017). Sleep problems in early psychosis are not only common but also complex (Dondé et al., 2022; Reeve, Sheaves, et al., 2019). The rates of comorbidity are high between different sleep disorder presentations, including insomnia, nightmares, circadian rhythm disruption, and hypersomnia (Reeve, Sheaves, et al., 2019). In qualitative accounts, young people at ultra-high risk of psychosis describe a range of sleep problems, including disrupted sleep timing and an irregular sleep

[2] *This chapter has been adapted from the following paper, attached in Appendix 2.1:*

Waite F, Cernis E, Kabir T, Iredale E Johns L, et al. (2023). A targeted psychological treatment for sleep problems in young people at ultra-high risk of psychosis in England (SleepWell): a parallel group, single-blind, randomised controlled feasibility trial. Lancet Psychiatry, 10: 706-18. https://doi.org/10.1016/ S2215-0366(23)00203-1

schedule, difficulties getting to sleep and sustaining sleep, and distressing nocturnal experiences such as night-time worry, hallucinatory experiences, and nightmares (Waite et al., 2018). The daytime effects include poor attendance and engagement at school or work, difficulties sustaining friendships and interacting in social situations, and a decline in mental health (Waite et al., 2018).

Evidence has been accumulating that chronic sleep disruption is not only common in patients with mental health conditions, but also that it can be successfully treated by cognitive behavioural approaches, and that this may lead to reductions in anxiety, depression, and psychotic experiences (Freeman, Sheaves, et al., 2020). As set out in Chapter 1, disrupted sleep may be a contributory causal factor in the occurrence of mental health disorders. However, there has been no randomised controlled trial testing the effects of sleep treatment for young patients who are especially vulnerable for a range of poor mental health outcomes: those identified in services as at ultra-high-risk of psychosis. On December 21, 2022, a search was conducted on PubMed (with no date or language restrictions) using the following search terms: ("sleep"[All Fields] OR "insomnia"[All Fields] OR "circadian rhythm disruption"[All Fields]) AND ("clinical high risk"[All Fields] OR "ultra high risk"[All Fields] OR "at risk mental state"[All Fields] OR "prodromal"[All Fields]) AND ("treatment"[All Fields] OR "intervention"[All Fields]). 50 papers were identified. There was no randomised controlled trial that had evaluated the treatment of sleep disruption in young patients at high risk for psychosis. There were six potentially informative studies identified in the search. Four longitudinal studies found that sleep disturbance in patients at ultra-high-risk of psychosis predicted the persistence of psychotic experiences over time (Lunsford-Avery et al., 2013, 2015, 2017; Zaks et al., 2021). The other two papers were the preliminary work underpinning this trial: a case series testing the brief, targeted sleep treatment with 12 young people at high risk of psychosis providing an initial indication of feasibility and potential benefit and an accompanying qualitative study that detailed that the treatment of sleep problems was highly valued by patients and that it had a meaningful impact on psychological wellbeing (Bradley et al., 2018; Waite et al., 2018).

2.1.2 Sleep problems: a potential treatment target

The gold standard treatment for insomnia, Cognitive Behavioural Therapy (CBTi) (NICE, 2022), has been successfully adapted for people with psychosis (Freeman, Waite, et al., 2015; Sheaves, Freeman, et al., 2018; Sheaves et al., 2019). Across the spectrum of severity of psychosis, large treatment effects on sleep problems have been consistently demonstrated (effect size range

Cohen's d = 0.9 to 1.9). There are also indications of potential further benefits on depression, anxiety, and psychotic experiences (Freeman, Waite, et al., 2015). Treatment effects on psychotic experiences may be mediated by affective symptoms (e.g. Bagrowska et al., 2022; Freeman et al., 2017; Kasanova et al., 2020; Reeve et al., 2018; Zaks et al., 2021). The thesis author further adapted the treatment specifically for young people at ultra-high-risk of psychosis. In an uncontrolled case series with 12 young patients, large improvements in sleep were found, with further smaller benefits on depression and psychotic experiences, with the changes maintained at one-month follow-up (Bradley et al., 2018). During the 10-week study period no participants transitioned to psychosis. In contrast, at the end of the study three participants no longer met the threshold for being at ultra-high risk of psychosis. The treatment was popular with high attendance rates and patients were keen to participate. In qualitative accounts young patients described the importance and value of gaining both knowledge ('learnt a lot') and skills ('developed a repertoire of skills') to improve sleep (Waite et al., 2018). Reflecting on the process of therapy, participants recognised negative expectations at the outset of the treatment, for example "I didn't think it would work at first". However, by gaining new insight and understanding of sleep and determined implementation of strategies, participants surprised themselves with the gains they made and valued the experience, for example saying: "I've quite enjoyed the therapy I've had" (Waite et al., 20218). Building on this preliminary case series work, the next step is to test the feasibility and seek confirmation of the potential benefits on sleep. In this feasibility RCT psychotic experiences were also measured, however only small effects would be expected, which this study was not powered to find. The findings of this feasibility RCT will set the parameters for a definitive trial to determine the effects on psychotic experiences.

2.1.3 This chapter

The aims of this trial were to assess the feasibility, acceptability, and establish the preliminary clinical efficacy of a targeted youth-focused intervention to improve sleep (SleepWell) and reduce psychotic experiences in young people at ultra-high-risk of psychosis.

The hypotheses related to clinical outcomes were:

1. Compared to usual care, the SleepWell therapy added to usual care would reduce insomnia and other sleep disruption (post-treatment).
2. Compared to usual care, the SleepWell therapy added to usual care would reduce psychotic experiences (a key marker of psychosis risk) and rates of transition to psychosis (post-treatment).

3. Compared to usual care, the SleepWell therapy added to usual care would reduce psychiatric symptoms (depression, anxiety, worry, suicidal ideation), increase activity and social functioning, improve physical health, and enhance quality of life (post-treatment).
4. Treatment effects would be maintained at follow-up.

As this was a feasibility trial, it was not powered to test for statistical significance with regard to these preliminary clinical outcomes. Further, due to limitations in statistical power, the focus was on determining any indication of effects of the sleep treatment on the dimension of psychotic experiences rather than relying solely on the dichotomous outcome of transition. In line with the findings from all previous studies, the expected effect of improving sleep on psychotic experiences was through improvements in negative affect (depression and anxiety), which is a mediator also of interest as an outcome in itself.

2. 2. Methods

2.2.1 Study design

This was a prospective, parallel group, single blind, single centre, randomised controlled feasibility trial of the SleepWell intervention with 3-month and 9-month follow-up conducted in two NHS mental health trusts in England: Oxford Health NHS Foundation Trust (OHFT) and Berkshire Healthcare NHS Foundation Trust (BHFT). The study received ethical approval from Health Research Authority (HRA/HRCW: IRAS 281235, The SleepWell trial) and NHS South Central – Oxford A Research Ethics Committee (20/SC/0281) (see appendices 2.2 – 2.4). The study was conducted in concordance with the Consolidated Standards of Reporting Trials (Montgomery et al., 2018) – appendix 2.5. The trial was prospectively registered (ISRCTN85601537) and the protocol (Waite, Kabir, et al., 2020) published at the start of the trial (and prior to patient recruitment; accepted 7th October 2020) (Appendix 1.1).

2.2.2 Contributions of the Lived Experience Advisory Panel

A Lived Experience Advisory Panel (LEAP) advised on the design and conduct of the trial. The LEAP was facilitated by the McPin Foundation – a charity that exists to 'put the lived experience of people affected by mental health problems at the heart of research' (www.mcpin.org). The LEAP consisted of four young people with lived experience of sleep disruption and psychotic like experiences. The LEAP contributed to the design of the study for example they: highlighted the

importance of self-initiated referral to ensure accessibility and inclusivity; advised on the age range of participants; advised on extending the follow up period from six to nine months; advised on the use of specific measures, such as the quality of life tools used in health economics evaluations; emphasised the importance of the planned provision of a one-off treatment session for those in the usual care alone arm; contributed to the format and content of the therapy manuals; and reviewed the trial protocol.

The LEAP met nine times throughout the duration of the trial. Brief newsletters were provided to all LEAP members every 2-3 months. They reviewed all patient facing documentation, including co-designing patient leaflets, posters, and dissemination materials. In these meetings they provided guidance and reflections on: conducting assessments remotely and using Personal Protective Equipment (PPE) which was required due to COVID-19 restrictions; recruitment strategies including potential locations to advertise the study (both online platforms and non-statutory services, for example university counselling services, drop-in cafes); how to explore potential negative effects of therapy during the qualitative studies and how this may be measured in future studies; public engagement methods for example co-designing information and materials for social media platforms; reviewing the study results and co-authoring the final outcome report; co-designing an infographic for participants summarising the study results; and dissemination routes and materials, including quotes and descriptions to be used in papers, podcasts, and funding applications. Following the results of the trial, the LEAP also contributed to the design and funding application for a definitive trial.

2.2.3 Participants

Participants were eligible if they were aged between 14-25 years, a patient of mental health services at the time of referral to the study, met diagnostic criteria for ultra-high-risk of psychosis on the Comprehensive Assessment of At Risk Mental States (CAARMS; Yung et al., 2005), were experiencing current sleep problems (identified by a score of $\geq$15 on the Insomnia Severity Index (ISI; Bastien et al., 2001), would like help to improve sleep, and were willing and able to give informed consent (or assent with parent/guardian consent for participants aged 14-15 years) for participation in the trial. Exclusion criteria were diagnosis of a primary severe mental health problem (including psychosis, bipolar disorder, personality disorder); likely primary diagnosis of sleep apnoea; a primary diagnosis of alcohol or substance disorder; organic syndrome; significant learning disability; or current engagement in any other individual psychological therapy. All

participants provided written informed consent, or assent with parent or guardian written consent for participants aged 14–15 years, before participation.

2.2.4 Randomisation and masking

Participants were randomly assigned (1:1) to either SleepWell therapy in addition to usual care or usual care alone. Randomisation was carried out by the trial coordinator using a validated and automated online system, Sortition, designed by the University of Oxford Primary Care Clinical Trials Unit. Allocation used a non-deterministic minimisation to ensure balance across groups with respect to severity of sleep disturbance (ISI score $\leq$21*vs* $\geq$22) and referring service (Early Intervention in Psychosis Service (EIS) *vs* Child and Adolescent Mental Health Service (CAMHS) *vs* Improving Access to Psychological Therapies service (IAPT)).

Trial assessors were masked to group allocation for all assessments. The trial coordinator informed all patients of the randomisation outcome, to ensure the trial assessors remained masked to group allocation. Precautionary strategies were taken to prevent unbinding of allocation and included: the staff member and assessor considered room use and booking arrangements; patients were reminded by the assessor not to talk about their allocation result; and, after the initial assessment, the assessor did not look at the patient's clinical notes. If group allocation was revealed, this was logged by the trial coordinator and the assessment was completed by another masked assessor. Assessors were unmasked on three occasions (two by 3 months and one additional by 9 months) and all assessments were successfully remasked.

2. 3 Procedures

2.3.1 The SleepWell therapy

The SleepWell therapy was designed to be delivered on an individual basis in up to eight one-hour sessions over a 12-week period. The prespecified minimum treatment dose was defined as four sessions. Additional contact between sessions (e.g., text messages, email) was provided to support the implementation of treatment strategies. The treatment was delivered by clinical psychologists, including the thesis author. Weekly clinical supervision was provided by the thesis author. The treatment sessions were conducted at the patient's home, at an NHS clinic, or adapted in light of COVID-19 restrictions for remote delivery. Flexibility in the location, duration, and number of sessions was provided to maximise engagement and uptake with this clinical group.

The SleepWell therapy is a psychological intervention designed for young people which targets three mechanisms that regulate sleep: sleep pressure, circadian rhythm, and hyperarousal (Borbély, 1982; Riemann et al., 2022; Saper et al., 2005).

1. To address sleep pressure, the need or propensity for sleep, the focus is on boosting daytime activity to increase night-time tiredness. The motivational benefits of fitness-trackers are used and there is a focus on morning routines to also assist with circadian alignment.
2. To address circadian alignment, the timing of sleep, sleep patterns are re-aligned with the environment by using light/dark exposure, which is the key zeitgeber, or time cue, for the sleep/wake cycle. Daily activity points (i.e. a specific activity at a set time), social connection, and mealtimes are also used to re-establish circadian rhythms.
3. To address hyperarousal, which can disrupt sleep despite high sleep pressure and circadian entrainment, strategies are employed to regulate levels of arousal. The key strategy is stimulus control in which patients relearn the association between bed and sleep. Other techniques include worry reduction strategies, cognitive restructuring techniques, and night-time relaxation.

The treatment is informed by standard CBT sleep protocols (Espie, 2006; Harvey, 2002) and protocols for treating sleep disruption in patients with psychosis (Waite, Myers, et al., 2016; Waite & Sheaves, 2020), with specific adaptations for the unique aspects of sleep in youth. These include biological changes in sleep architecture such as the delayed circadian sleep phase, as well as lifestyle factors such as exam pressure, social networks, and environmental constraints (for example, shared accommodation with siblings or at university).

The SleepWell intervention is manualised in a modular format. It includes five core modules and four further modules used based on individualised formulation, need, and patient preference. The format and manuals were developed in collaboration with the LEAP.

The first module covers psychoeducation about sleep disruption and the key factors needed for good sleep, assessment of the current sleep difficulties and maintaining factors, formulation, and goal setting. The assessment includes a checklist of factors which commonly disrupt sleep (e.g. absence of a consistent sleep schedule; inactivity in the daytime; worry at night; nightmares; hearing voices at night; and environmental and lifestyle factors such as too much light in the bedroom at

night or high caffeine intake) (Waite, Myers, et al., 2016; Waite & Sheaves, 2020). This enables the young person to self-identify maintaining factors which can be used to build the formulation and to identify treatment targets. Within the goal setting segment an ideal 'sleep window', a period of time in which the young person would like to be asleep, is established. Achieving sleep within the ideal sleep window is often a primary focus of treatment.

To achieve the treatment goals there are three core treatment modules, with four additional modules which can be selected by patients on the basis of individual need enabling the intervention to be personalised. The first core treatment module focuses on establishing the environmental and lifestyle context for sleep. This includes 'setting the scene' for sleep by ensuring there is a sleep-promoting environment (a comfortable bed, in a space/room that is sufficiently dark at nighttime) and limiting the effects of modifiable lifestyle factors such as the quantity and timing of caffeine intake. The second focuses on stimulus control and strategies to reduce hyperarousal. This includes learning to reassociate the bed with sleep. To achieve this, a wind-down routine helps to calm the mind and prepare for the transition from wakefulness to sleep. Worries, fears, frustrations, or rumination at night-time are addressed and the day is 'put to rest'. The third focuses on circadian entrainment (using light/dark exposure, setting the sleep window, and/or boosting zeitgebers, for example, meal and activity times). Given the common shift in adolescence to a delayed phase circadian pattern, additional emphasis was put on establishing a consistent sleep window and then adjusting the timing of this to align with the young person's ideal time. For many young people there were societal constraints on this, such as school start times or working night shifts. The additional treatment modules cover nightmares, unusual experiences such as hearing voices or seeing shapes or figures, and further work to reduce night-time worry and promote relaxation. The final module focuses on consolidating learning, setting future goals, and relapse prevention.

The key adaptions for individuals at ultra-high-risk of psychosis include: addressing the developmental issue of delayed-phase circadian patterns; establishing a sleep team to support the young person by engaging family, friends, and school teachers; addressing psychotic experiences that affect sleep; problem solving around constraints on stimulus control due to the sleep environment (e.g. sharing a bedroom with a sibling, or the bedroom needing to be used for study or socialising); and navigating external stressors that affect sleep (e.g. living independently for the first time or taking exams). Formal sleep restriction was not used due to not wanting to cause any large reduction in sleep time on any given night during treatment.

With patient consent, sessions were audio-recorded to check the quality of the therapy. Tapes were rated for fidelity and competence using the Revised Cognitive Therapy Scale (CTSR). All tapes assessed were rated as providing at least satisfactory cognitive therapy (i.e. a score of at least 3 on each CTSR item). Therapists completed a treatment adherence tool at the end of each session reporting the key strategies and techniques covered in the session (appendix 2.6). The tool listed 12 items related to sleep specific content and techniques, such as addressing the sleep environment, agreeing the sleep window (including key anchor times such as bed time and rise time), and stimulus control. The tool also listed seven items related to standard CBT strategies such as completing measures, setting and reviewing between-session tasks, and engagement.

At the end of their participation in the study (after completion of the final assessment), participants in the usual care alone group were offered a one-off session with a clinical psychologist. This session briefly identified a plan to improve sleep, which participants could then implement independently. The importance of offering this session was emphasised by the LEAP.

2.3.2 Usual care

SleepWell was provided in addition to usual care. Usual care was recorded using the Client Service Receipt Inventory (CSRI; Beecham & Kanpp, 1992), with psychiatric admissions and medication recorded from electronic medical records. Usual care typically consisted of infrequent contact with a general practitioner or mental health professional for assessment, and prescription of psychotropic medication (most often antidepressant medication) as needed. There were no changes to usual care as a result of participating in the trial.

2.3.3 Assessment schedule

Study assessments were conducted at 0 months (baseline, before randomisation), 3 months (post intervention), and 9 months after randomisation.

2.4 Outcomes

2.4.1 Primary outcomes: Feasibility and acceptability

The primary objective was to assess the feasibility and acceptability of a targeted sleep intervention to prevent psychosis in young people at ultra-high-risk of psychosis. The key markers of feasibility

were rates of recruitment, retention, data completion, and treatment uptake. The definition of each marker reported in this trial is detailed below.

2.4.1.1 Recruitment

- *Number of patients identified:* Including all patients who were identified as eligible for the trial.
- *Number of patients recruited:* Expressed as the number of patients recruited (i.e. the number of patients randomised) as a percentage of all participants that were identified as eligible for the trial.
- *Number of patients declined:* Defined as the number of patients who declined to participate (i.e. declined to be randomised) reported as a percentage of the total number of patients identified as eligible for the trial.
- *Number of referrals made per site, and per service type, per month*: Referrals were reported by site (Oxford Health NHS Foundation Trust or Berkshire Healthcare NHS Foundation Trust) and by service type (specialist early intervention in psychosis services (EIP: ages over 14 years), child and adolescent mental health services (CAMHS: ages 0-18 years) or Adult Mental Health team/Community Mental Health Team/ Improving Access to Psychological Therapies service (AMHT/CMHT/IAPT: ages over 18 years), and Common Point of Entry/Single Point of Access (CPE/SPA).

2.4.1.2 Retention

- *Retention at 3 months:* The number of patients with follow-up data at 3 months (post-intervention) / total number of patients randomised.
- *Retention at 9 months:* The number of patients with follow-up data at 9 months (post-intervention)/total number of patients randomised

2.4.1.3 Data completion

- *Completion rate of each assessment measure, including wearable-tech devices:* Completion rates were computed for each assessment measure listed under secondary objectives at each time point. This was calculated as the number of assessment measures completed/the number of participants randomised.
- *Time taken to complete assessments:* The mean (SD) for time to complete all assessments.

2.4.1.4 Treatment uptake

- *Location and Attendance at treatment sessions:* In the intervention arm the location and number of treatment sessions were recorded. The mean number of sessions attended and percentage attended are presented.

2.4.1.5 Treatment acceptability

- *Acceptability of the sleep intervention:* At the last treatment session, patients completed the Abbreviated Acceptability Rating Profile (AARP; Tarnowski & Simonian, 1992). This is an 8-item questionnaire with responses ranging from 1 (strongly disagree) to 6 (strongly agree). The total score has a range from 8 to 48. Higher scores indicate greater acceptability of the treatment.

2.4.2 Secondary outcomes: Preliminary clinical outcomes

The secondary research objective was to gather data on clinical outcomes to provide a preliminary indication of clinical efficacy. In line with the main clinical target of the intervention, the primary outcome for the clinical hypotheses was insomnia, assessed using the Insomnia Severity Index (ISI; Bastien et al., 2001), and used as an indication of efficacy on sleep. The key secondary outcomes were psychotic experiences, measured using the CAARMS (Yung et al., 2005) and Revised Green et al. Paranoid Thoughts Scale (RGPTS; Freeman et al., 2021), and affective symptoms (shown to be a mediator of the relationship between sleep disturbance and psychotic experiences) measured using the Depression, Anxiety Stress Scales (DASS-21; Lovibond & Lovibond, 1995). Higher scores on each of these measures indicates greater severity. Further details of all measures are provided below.

2.4.2.1 Key secondary outcomes

2.4.2.1.1 Insomnia Severity Index (ISI)

The Insomnia Severity Index (ISI; Bastien et al., 2001) is a seven item self-report scale assessing symptoms of insomnia - see appendix 2.7. Each of the seven items is scored from 0 to 4, giving a possible range for the total score of 0 to 28. Higher scores indicate greater levels of insomnia. The scale has adequate internal consistency ($\alpha = 0.76$). The total score can be interpreted as follows: absence of insomnia (0-7); sub-threshold insomnia (8- 14); moderate insomnia (15-21); and severe insomnia (22-28). A score of 15 or above is identified as the optimal score for indicating clinical

insomnia. In addition, the scale has good internal consistency in youth (α = 0.83) where the optimal total score for detecting clinical insomnia was 9 or above (Chung et al., 2011).

2.4.2.1.2 Comprehensive Assessment of At-Risk-Mental-States (CAARMS)

The Comprehensive Assessment of At-Risk-Mental-States (CAARMS; (Yung et al., 2005) is a researcher administered semi-structured assessment tool - see appendix 2.8. The CAARMS can be used to give an assessment of symptom severity and at-risk status. It is the standard tool for identifying help-seeking people at-risk of psychosis. The brief CAARMS (2016) used in this study, comprises four psychotic experiences subscales: Unusual Thought Content (UTC; e.g. ideas of reference, delusional mood, thought insertion), Non-Bizarre Ideas (NBI; e.g. persecutory ideas, grandiose ideas), Perceptual Abnormalities (PA; e.g. visual or auditory changes), and Disorganised Speech (DS; e.g. circumstantial or tangential speech). Each subscale is rated by the interviewer for severity (rated from 0 never/absent to 6 severe, indicative of clinical psychosis level) and frequency and duration (rated from 0 to 6, where 0 is absent, and 6 is continuous). A total severity score for each subscale is calculated as the product of severity and frequency/duration, giving a score for each scale ranging from 0-36. The total score was then calculated as the sum of the four subscales, with a range of 0-144. Higher scores on all scales indicate greater severity.

At-risk status is operationalised on the CAARMS under three categories: vulnerability group (family history and drop in functioning), attenuated psychotic experiences (subthreshold intensity or subthreshold frequency), and brief limited intermittent psychotic symptoms (BLIP; clinical threshold psychotic symptoms that remitted spontaneously within one week). In this study, participants were categorised as either being under CAARMS threshold, at-risk of psychosis (based on the above CAARMS criteria), or first-episode psychosis (based on the CAARMS threshold). At follow-ups, direction of change between categories is reported in comparison to all preceding timepoints.

2.4.2.1.3 Revised Green et al Paranoid Thoughts scale (RGPTS)

The Revised- Green et al Paranoid Thoughts scale (RGPTS; Freeman et al., 2021) is a self-report measure with two subscales: ideas of reference (part A) and ideas of persecution (part B) - see appendix 2.9. Ideas of reference comprises of 8 questions with possible responses ranging from 0 (not at all) to 4 (totally). The possible range of scores is 0 to 32. Ideas of persecution comprises of 10 questions with possible responses ranging from 0 (not at all) to 4 (totally). The possible range of scores is 0 to 40. The scale has high reliability across the spectrum of paranoia severity (α >

0.90). Scores can be interpreted using the following ranges: Average (Reference: 0–9; Persecution: 0–4); elevated (Reference: 10–15; Persecution: 5–10); moderately severe (Reference: 16–20; Persecution:11–17); severe (Reference: 21–24; Persecution: 18–27); and very severe (Reference: 25+; Persecution: 28+). Recommended cut-offs on the persecution scale are: 11 (clinical levels of persecutory ideation); 18 (likely persecutory delusion). The scale has been validated for use in adults and adolescents (e.g. Schlier et al., 2024).

2.4.2.1.4 Depression, Anxiety and Stress Scale (DASS-21)

The Depression, Anxiety and Stress Scale (DASS-21; Lovibond & Lovibond, 1995) is a 21-item self-report questionnaire consisting of three subscales, each reported separately: Depression, Anxiety, and Stress - see appendix 2.10. Each question has responses ranging from 0 (never) to 3 (almost always). The following items were summed to give total scores for each subscale. Depression items: 3, 5, 10, 13, 16, 17, 21; Anxiety items: 2, 4, 7, 9, 15, 19, 20; and Stress items: 1, 6, 8, 11, 12, 14, 18. Cronbach's alphas for the DASS-21 subscales were .94 for Depression, .87 for Anxiety, and .91 for Stress (Antony et al., 1998). As the DASS-21 is a short form version of the DASS-42, the total score was then multiplied by 2 and given the following severity ratings: normal (Depression: 0-9; Anxiety: 0-7; Stress: 0-14), mild (Depression: 10-13; Anxiety: 8-9; Stress :15-18), moderate (Depression: 14-20; Anxiety: 10-14; Stress: 19-25), severe (Depression: 21-27; Anxiety: 15-19; Stress 26-33), and extremely severe (Depression: 28+; Anxiety 20+; Stress 34+). The scale has been validated for use in adults and adolescents (e.g. Szabó, 2010).

2.4.2.2 Other clinical outcomes

Other clinical measures assessed sleep using different methods: a sleep diary and a second self-report measure focused on circadian rhythm (SLEEP-50 Circadian Rhythm Disruption: CRD; Spoormaker et al., 2005).

Additional measures of psychotic experiences included hallucinatory experiences (Specific Psychotic Experiences Questionnaire – Hallucinations subscale: SPEQ-H; Ronald et al., 2014) and dissociation (Černis Felt Sense of Anomaly Scale: ČEFSA; Černis et al., 2021).

Further measures of psychiatric symptoms included suicidal ideation (Columbia Suicide Severity Rating Scale: CSSRS; Posner et al., 2011), worry (Dunn Worry Questionnaire: DWQ; Freeman et al., 2020), and beliefs about the self (Brief Core Schema Scale: BCSS; Fowler et al., 2006).

Measures of activity and social functioning included: daily activity (Time budget; Hodgekins et al., 2015), functioning (The Work and Social Adjustment Scale: WSAS; Mundt et al., 2002), and agoraphobic avoidance (Oxford Agoraphobic Avoidance Scale: O-AS; Lambe et al., 2021).

Measures of physical health included: body mass index (BMI), step count (measured using an actigraphic wearable tech device), body esteem (Body Esteem Scale for Adults and Adolescents: BESAA; Mendelson et al., 2001), substance use (Maudsley Addiction Profile: MAP; Marsden et al., 1998), and overall physical health (Patient Health Questionnaire: PHQ-15; Kroenke et al., 2002).

Measures of quality of life included: recovery (Questionnaire about the Process of Recovery (Questionnaire of the Process of Recovery: QPR; Law et al., 2014) and quality of life (ReQoL; Keetharuth et al., 2018) and EQ5D).

Service use was measured using the CSRI (Beecham & Kanpp, 1992). Medication and admissions were recorded from medical records.

The CAARMS, CSSRS, Time budget, and CSRI were clinician administered. BMI was calculated by patient reported height and weight. Step count was measured using an actigraphic wearable tech device. All other measures were self-report. All outcome measures were collected at each assessment timepoint.

Further details of all outcome measures including the scoring method used is reported in the statistical analysis report (available in the supplementary materials of the published trial outcome paper: Waite et al., 2023).

2.4.3 Adverse events

Safety outcomes included patient-reported adverse events during trial participation. A serious adverse events (SAE) was defined as any untoward medical occurrence that results in death, is life-threatening, requires or prolongs hospital admission, or results in persistent or clinically significant disability or incapacity. The sorts of SAEs that can typically occur in this participant group include: deaths, suicide attempts, serious violent incidents, and admissions to hospital. Hospitalisation for a pre-existing physical health condition, including elective procedures planned prior to study entry, which had not worsened, did not constitute an SAE.

In line with the standard operational procedure of the trial, the occurrence of all SAEs was recorded. Electronic medical records were systematically checked for SAEs following completion of the final assessment. Formal complaints about therapy, and transition to psychosis were also recorded. Transition to psychosis was determined through multiple sources including: scoring above psychosis threshold on the CAARMS at the research assessments; review of medical records; clinical team feedback; prescription of antipsychotic medication; and the clinical observation of the study therapist. An independent data monitoring and ethics committee (DMEC) chair rated whether any SAE was related to the trial procedures or intervention.

2.5 Changes to the protocol

COVID-19 restrictions were in place throughout the recruitment period, including two periods of national lockdown in England (starting in November 2020 and January 2021). Remote working practices were used and measures such as wearing PPE remained in place throughout the follow-up period. An additional exclusion criterion was added: moderate or high risk for a severe course of COVID-19. This was modified in February 2021, so that when an individual at moderate or high risk had been vaccinated, they could then enter the trial.

2.6 Statistical analysis

The statistical analysis plan was approved by the data monitoring and ethics committee before any inspection of post-randomisation data. The statistical analysis plan and full statistical report are available in the supplementary materials of the published trial outcome paper: Waite et al., 2023. This trial is registered with the ISRCTN registry: ISRCTN85601537.

The sample size was calculated in accordance with the feasibility aims of the trial. A sample size of 20 per randomised group (40, in total across the study) was calculated to be sufficient to estimate a recruitment rate of 50% with a 95% CI of 35% to 65% and a retention rate of 80% with a 95% CI of 65% to 90% (PASS version 12). This was also determined to be sufficient to estimate the variability of outcome measures for future sample size calculations, with 12 per arm sufficient for estimation of the variability for the purpose of sample size calculations (Julious, 2005). The trial was not powered to detect a significant difference between treatment groups.

For the feasibility markers, analysis was descriptive in nature and no hypothesis testing was carried out. Numbers and proportions were presented for binary feasibility measures (i.e. recruitment and

retention, uptake of treatment, and data completion) overall and by randomised group. Continuous measures were presented using the mean and standard deviation (or median and IQR where required). For feasibility markers, there were prespecified progression criteria to inform the design of a future definitive trial including stop, amend, or proceed. For recruitment, the proceed criterion for a future trial was a mean rate of at least two participants per month. For treatment uptake, consent by eligible participants, retention, and data collection, the proceed criterion for a future trial was a rate of at least 75%, 51% to 75% indicates the need to amend, and below 50% indicates stop.

For the primary and secondary clinical outcomes, linear mixed effects models were used. Baseline score of the outcome of interest, time, treatment group, and a time x treatment interaction were included as fixed effects and participant as a random effect. The treatment effect estimate is reported as the adjusted mean difference between groups and 95% CIs. In addition, estimates for Cohen's *d* effect sizes, at each time point, as the adjusted mean difference of the outcome (between the groups) divided by the baseline SD of the outcome are reported. An effect size of 0.2 is considered a small effect, 0.5 considered a medium effect, and 0.8 or higher a large effect (Cohen, 1988, 1992). Results were graphically presented in a forest plot. No p-values are reported for any outcomes as this is a feasibility trial. For the other clinical outcomes the analysis is descriptive with no hypothesis testing conducted.

Receipt of the intervention, participation to follow-up, and adverse events were fully documented among all recruited participants. Clinical outcomes are reported by randomised group for all participants randomly assigned (intention-to-treat analysis). All participants with available data were included in all analyses of feasibility and clinical outcomes in the treatment group to which they were randomised. Safety was assessed in all randomly assigned participants.

All analyses were done in Stata (version 16.1). The forest plot was produced in Microsoft Excel (version 2306).

2.7 Role of the funding source

The funder of the study had no role in the design, data collection, data analysis, data interpretation, or writing of the draft.

2.8 Results

2.8.1 Primary outcomes: Feasibility and acceptability

Recruitment took place from 18th November 2020 to 26th January 2022 (this included 11 months with restrictions on face-to-face contact due to COVID-19), with final follow-up data collected on 21st September 2022. Of 163 patients referred, 67 patients completed screening, and 40 (59.7% of those screened) were enrolled and randomly assigned to the SleepWell intervention in addition to usual care (n=21) or usual care alone (n=19) (Figure 2.1).

The mean age of participants was 16.9 years (SD =2.5, range 14 to 23 years). Most participants identified as either female (n=19, 47.5%) or male (n=19, 47.5%). The majority of participants were White (n=32, 80.0%), living with their parents (n=35, 87.5%), in full-time education or training (n=27, 67.5%), and just under half were prescribed psychotropic medication, predominantly antidepressants (n=17, 42.5%) (Table 2.1). The ISI scores at baseline indicate that participants had moderate insomnia (mean=18.9, SD=3.0), with 9, 22.5%, of participants in the severe range (a score of 22 or above). Measured on the DASS-21, participants had levels of depression (mean=29.0, SD=11.4) and anxiety (mean=23.3, SD=11.6) in the extremely severe range, and on the RGPTS levels of paranoia in the moderately severe range (ideas of reference: mean=18.2, SD=9.1; persecutory ideation: mean=16.9, SD=11.80). Measured on the SPEQ-H, 26 (65.0%) participants heard voices on at least a weekly basis. Half the participants (n=20, 50.0%) were experiencing active suicidal thoughts, as measured on the CSSRS.

All progression criteria related to rates of recruitment, retention, data collection, and treatment uptake were achieved. Sixty-seven patients were screened for eligibility, and 40 (59.7% of those screened) were enrolled. No eligible participants declined. Two eligible participants were unreachable after screening. One eligible participant withdrew consent prior to randomisation. There were no withdrawals following randomisation. All participants provided data at at least one follow-up timepoint. However, there was one missed assessment at each follow-up timepoint – giving a follow up rate of 97.5%. 116 (71.2%) referrals were received from OHFT and 27 (28.8%) from BHFT. Most referrals were received from EIS (n=104, 63.8 %) or CAMHS (n=39, 23.9%), with few from other adult mental health services (appendix 2.11). Data completion rates for outcome measures at post-treatment (3-month) were at least 87.5% for self-report measures, with lower rates on sleep diary (n=26, 65%), step count using an actigraphy device (n=26, 65%), and

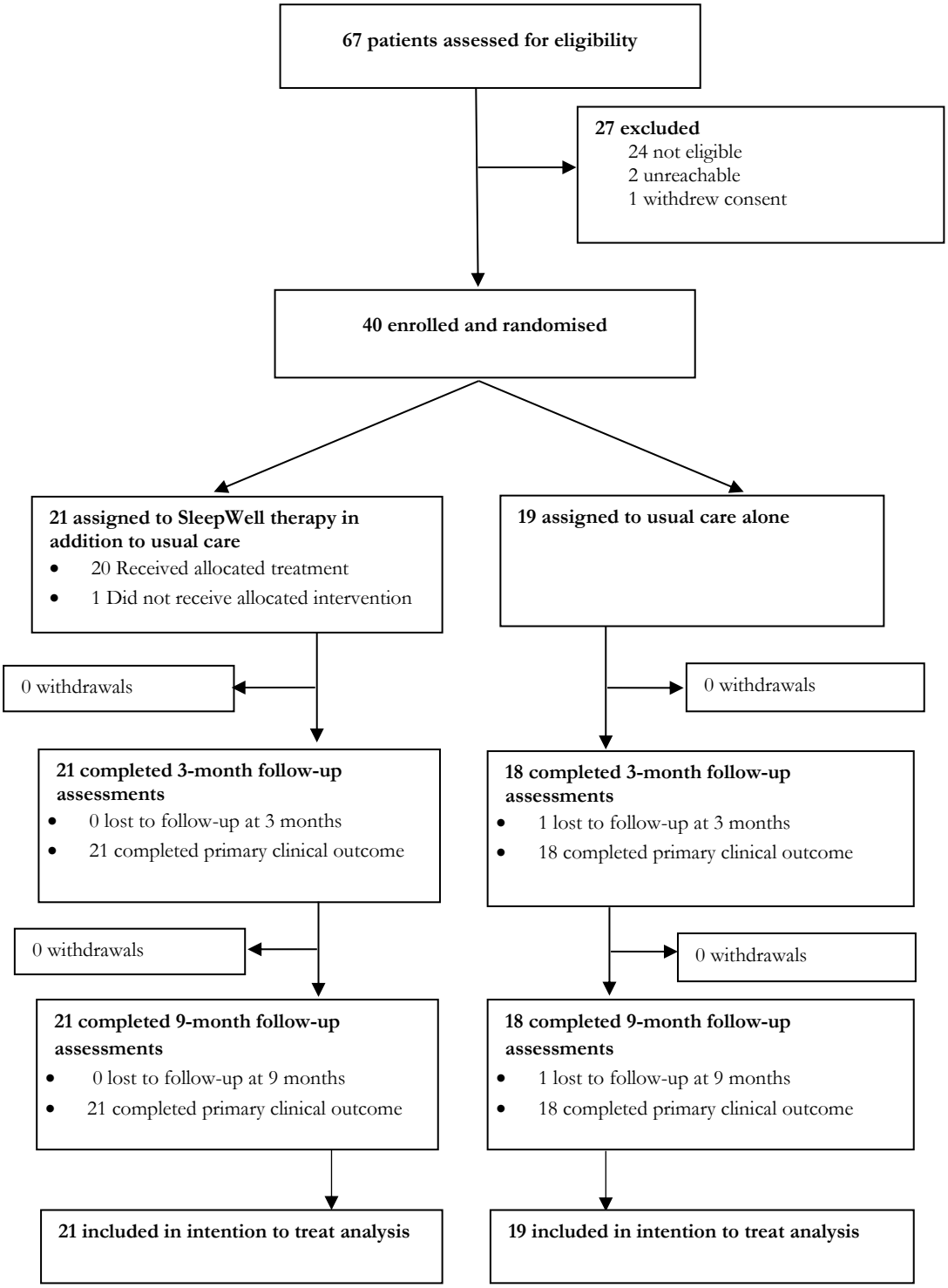

Figure 2.1. Trial profile.

BMI (n=30, 75%) (appendix 2.12). At 9 months, data completion rates remained high with at least 92.5% (n=37) for self-report measures. At baseline most assessments were completed remotely (either fully n=25, 62.5% or partially n=12, 30%). The mean time to complete the assessments was 171.8 minutes (SD = 55.0) at baseline, 117.9 minutes (SD = 46.8) at 3 months, and 104.7 minutes (SD = 43.9) at 9 months. All participants with available data were included in all analyses in the treatment group to which they were randomised.

Table 2.1. Participant demographic characteristics.

	Usual care alone (n=19)	**SleepWell therapy (n=21)**	**All participants (n=40)**
Age (years) mean (SD) [range]			
	16.8 (2.8) [14.0 - 22.0]	17.0 (2.2) [14.0 - 23.0]	16.9 (2.5) [14.0 - 23.0]
Gender n (%)			
Female	8 (42.1)	11 (52.4)	19 (47.5)
Male	9 (47.4)	10 (47.6)	19 (47.5)
Other	2 (10.5)	0 (0.0)	2 (5.0)
Ethnicity n (%)			
White	15 (78.9)	17 (81.0)	32 (80.0)
Black British	0 (0.0)	1 (4.8)	1 (2.5)
Black Caribbean	0 (0.0)	1 (4.8)	1 (2.5)
Indian	1 (5.3)	0 (0.0)	1 (2.5)
Pakistani	1 (5.3)	0 (0.0)	1 (2.5)
Other	2 (10.5)	2 (9.5)	4 (10.0)
Age first in contact with mental health services (years) mean (SD) [range]			
	14.5 (3.2) [7.0 - 21.0]	15.0 (3.3) [10.0 - 23.0]	14.8 (3.2) [7.0 - 23.0]
Living Situation n (%)			
Living with Parents	17 (89.5)	18 (85.7)	35 (87.5)
Living with Partner	1 (5.3)	2 (9.5)	3 (7.5)
Living with Others	1 (5.3)	0 (0.0)	1 (2.5)
Missing	0 (0.0)	1 (4.8)	1 (2.5)
Employment Type n (%)			
School student or full-time	11 (57.9)	16 (76.2)	27 (67.5)
HEI student or training full-time	2 (10.5)	1 (4.8)	3 (7.5)
Employed full-time (paid)	2 (10.5)	3 (14.3)	5 (12.5)
Employed part-time (paid)	1 (5.3)	0 (0.0)	1 (2.5)
Unemployed (on benefits)	0 (0.0)	1 (4.8)	1 (2.5)
Unemployed (not on benefits)	2 (10.5)	0 (0.0)	2 (5.0)
Other	1 (5.3)	0 (0.0)	1 (2.5)
Prescribed psychotropic medication n (%)			
Currently prescribed psychotropic medication	7 (36.8)	10 (47.6)	17 (42.5)
Mean number of prescribed psychotropics	1.6 (0.5)	1.3 (0.5)	1.4 (0.5)
Currently prescribed antipsychotic medication	1 (5.3)	0 (0.0)	1 (2.5)
Currently prescribed antidepressant medication	7 (36.8)	10 (47.6)	17 (42.5)
Currently prescribed anxiolytic medication	0 (0.0)	0 (0.0)	0 (0.0)
Currently prescribed mood stabilisers	1 (5.3)	0 (0.0)	1 (2.5)
Currently prescribed hypnotic medication	2 (10.5)	2 (9.5)	4 (10.0)

2.8.2 Treatment uptake, content, and acceptability

Treatment uptake rates were 95% (20 of 21 participants received the prespecified treatment dose of at least four sessions of the intervention). The mean number of sessions attended was 7.71

(SD=2.12; range 2 to 12, n=21). The mean number of sessions missed (did not attend/cancelled) was 1.19 (SD=1.69). In total 162 sessions were provided (86.6% of the 187 sessions offered). These were held at: the patient's home n=54 (33.3%), in the clinic n=43 (26.5%), or remotely n=65 (39.5%). For remote sessions these were via videocall n=56 (86.2% of remote sessions, 34.6% of all sessions) or via telephone n=9 (13.8% of remote sessions, 5.6% of all sessions). PPE was used in all in-person sessions. All participants received between session contact as part of the therapy. The frequency of contact was determined by patient choice.

In line with the treatment protocol, all participants developed an individualised maintenance cycle formulation of their sleep difficulties (see Table 2.2). Difficulty getting to sleep before the early hours was the most common presentation (only 5 (17.9%) of the 28 participants who completed a sleep diary at baseline had a midpoint sleep time between 2am-4am). Yet within this common presentation there were differences in the individual formulation. These followed three main patterns related to the primary factor driving the sleep disturbance: for some participants this presentation was driven by a shift in circadian timing (delayed-sleep phase) and therefore not feeling tired until later (or waking until late in the morning); for others there were heightened levels of arousal in the evening (perhaps lying in bed trying to sleep and experiencing frustration, or the mind racing with worries, or seeing visions or hearing voices); and for others there was insufficient sleep pressure due to low levels of activity in the daytime. When the primary driver was disrupted timing, the focus of treatment was to set then incrementally shift the sleep window, using the morning rise-up routine to drive this change complemented with the evening wind-down routine to prepare for sleep. When the primary issue was elevated arousal, the key approach was to reduce levels of arousal in the evening (via a wind-down routine) and re-associate the bed with sleep, adding specific worry reduction strategies and work addressing psychotic experiences as needed in the latter phase of the therapy. Lastly, to address insufficient sleep pressure the focus was on setting a rise-up routine and increasing daytime activity. Yet many patients described a combination of all three factors. This reflects the complexity of sleep problems in this patient group.

In line with these sleep presentations and formulations, the most commonly used techniques to improve sleep were establishing wind-down and rise-up routines (n=20, 95%) to help transition between wakefulness and sleep (and vice versa). These techniques were used with all but one participant and utilised in nearly half the treatment sessions. The second most frequently used technique was setting a specific period for sleep, the 'sleep window', with key anchor times for bed and wake (n=17, 81%). Approaches focused on coping with psychotic experiences at night time

were used with a minority of participants (n=4, 19%). Despite the option to use actigraphy data in the treatment, this was not incorporated as a key technique for any patients.

Table 2.2. Summary of sleep therapy techniques used in SleepWell therapy sessions.

Sleep therapy techniques	Total participants that received the technique	Total number of times technique was used
	n (%) participants	n (%) sessions
Psychoeducation and normalising about sleep	21 (100)	54 (33)
Developing maintenance cycle formulation	21 (100)	38 (23)
Addressing sleep environment	13 (62)	27 (17)
Identifying and agreeing sleep window (key anchor times: bed and wake)	17 (81)	63 (39)
Wind-down (including relaxation) and rise-up routines	20 (95)	76 (47)
Stimulus control	16 (76)	32 (20)
Establishing a daytime routine: increasing activity with circadian rhythm	13 (62)	22 (14)
Utilising actigraphy data	0 (0)	0 (0)
Addressing night-time worry	12 (57)	21 (13)
Managing nightmares and night-time awakenings	3 (14)	3 (2)
Coping with psychotic-like experiences which impact on sleep	4 (19)	10 (6)
Establishing a sleep team	8 (38)	9 (6)

Note. The total number of sessions received by all participants was 162 sessions.

All participants completed in-session measures, with measures completed in 92% (n=149) of sessions (see Table 2.3). All participants established a between-sessions tasks to implement strategies, with tasks set in 81% (n=131) of sessions. Consistent with the core content covered during sessions, the most frequent homework task was implementing wind down routines (n=18, 85.7%). Stimulus control (n=12, 57.1%), rise up routines (n=10, 47.6%), and increasing daytime activity (n=9, 42.9%).

Table 2.3. Summary of Core CBT techniques used in SleepWell therapy sessions.

Core CBT techniques	Total participants that received the technique	Total number of times technique was used
	n (%) participants	n (%) sessions
Complete measures	21 (100)	149 (92)
Establish homework task	21 (100)	131 (81)
Review homework/progress	20 (95)	125 (77)
Active and purposeful engagement	14 (67)	36 (22)
Dealing with a distressing event from the past week	12 (57)	23 (14)
Enhancing motivation	6 (29)	8 (5)
Establishing a therapy 'blueprint'	18 (86)	26 (16)

Note. The total number of sessions received by all participants was 162 sessions.

For half of participants, at least one session included time spent discussing and responding to a distressing current event. This included difficulties in relationships and friendships, suicidal intent and action, exam stress, and changes to living situations.

The median treatment acceptability score, measured on the AARP, was 48 (IQR=46 to 48, maximum total score=48, n=17) (see Table 2.4).

Table 2.4. Treatment acceptability.

	n	Min	Max	Mean	SD
This was an acceptable treatment for me	17	4	6	5.71	0.686
This treatment has been effective in alleviating my sleep problems	17	3	6	5.59	0.870
My sleep problems were severe enough to justify the use of the treatment	17	4	6	5.65	0.606
I would be willing to undergo this treatment again	17	4	6	5.82	0.529
This treatment did not have bad side effects	17	4	6	5.59	0.712
I liked this treatment	17	4	6	5.76	0.664
The treatment was a good way to handle my sleep problems	17	4	6	5.76	0.664
Overall, the treatment was helpful	17	5	6	5.88	0.332
Treatment Acceptability scale total	17	33	48	45.76	4.409

Note. Each item is rated on a scale of 1-6, giving an overall total maximum score of 48.

2.8.3 Secondary outcomes: Preliminary clinical outcomes

The primary clinical outcome was insomnia, assessed using the ISI. The key secondary outcomes were psychotic experiences, measured using the CAARMS and RGPTS, and affective symptoms measured using the DASS-21. Table 2.5 summarises the primary and key secondary clinical outcome data.

Compared to the usual care alone group, the SleepWell therapy group had large effect size reductions in sleep disturbance at 3 months (ISI adjusted mean difference=-8.12, 95% CI –11.60 to – 4.63, Cohen's *d* =-2.67, 95% CI -3.81 to -1.52) and 9 months (ISI adjusted mean difference=-5.83, 95% CI -9.31 to – 2.35, Cohen's *d* =-1.91, 95% CI -3.06 to -0.77,. Post-treatment, 16 (76.2%) participants in the treatment group were below the cut-off for insomnia (a score of 0-7 on the ISI), compared to two (11.1%) participants in the control group. There were also reductions in depression, anxiety, and paranoia (see Figure 2.2).

Table 2.5. Summary statistics for the clinical outcome data.

	Usual care alone (n=19)	SleepWell therapy (n=21)	Adjusted Mean Difference [95% C.I.] [1]
Insomnia Severity Index Total Score, mean (SD) [n]			
Baseline	18.7 (3.3) [19]	19.2 (2.8) [21]	-
3 months	14.3 (5.8) [18]	6.3 (4.9) [21]	-8.12 [-11.60 to -4.63]; Std. effect: -2.67 [-3.81 to -1.52]
9 months	13.9 (5.8) [18]	8.3 (6.3) [21]	-5.83 [-9.31 to -2.35]; Std. effect: -1.91 [-3.06 to -0.77]
CAARMS Symptom Severity Total Score, mean (SD) [n]			
Baseline	45.4 (12.1) [19]	50.8 (11.2) [21]	-
3 months	44.6 (21.6) [16]	42.2 (20.9) [19]	-6.83 [-20.60 to 6.94]; Std. effect: -0.58 [-1.75 to 0.59]
9 months	39.3 (26.6) [18]	38.8 (21.4) [20]	-3.44 [-16.81 to 9.92]; Std. effect: -0.29 [-1.43 to 0.84]
RGPTS-A Total Score (Ideas of Reference), mean (SD) [n]			
Baseline	17.6 (9.5) [19]	18.7 (8.9) [21]	-
3 months	15.9 (11.1) [17]	13.2 (8.9) [20]	-4.70 [-10.03 to 0.63]; Std. effect: -0.52 [-1.10 to 0.07]
9 months	15.9 (11.2) [18]	10.4 (9.5) [21]	-5.90 [-11.11 to -0.69]; Std. effect: -0.65 [-1.22 to -0.08]
RGPTS-B Total Score, (Ideas of Persecution) mean (SD) [n]			
Baseline	14.7 (11.9) [19]	18.9 (11.7) [21]	-
3 months	14.5 (13.3) [17]	14.4 (11.7) [20]	-4.51 [-10.99 to 1.97]; Std. effect: -0.38 [-0.93 to 0.17]
9 months	15.5 (15.5) [18]	10.3 (10.1) [21]	-7.73 [-14.07 to -1.39]; Std. effect: -0.65 [-1.19 to -0.12]
DASS-21 Total Depression Score, mean (SD) [n]			
Baseline	27.5 (12.4) [19]	30.4 (10.5) [21]	-
3 months	21.3 (14.6) [17]	19.5 (13.4) [19]	-4.00 [-11.47 to 3.47]; Std. effect: -0.35 [-1.01 to 0.31]
9 months	19.8 (14.8) [16]	14.7 (10.2) [21]	-7.66 [-15.09 to -0.22]; Std. effect: -0.67 [-1.33 to -0.02]
DASS-21 Total Anxiety Score, mean (SD) [n]			
Baseline	20.3 (12.6) [19]	26.0 (10.1) [21]	-
3 months	17.9 (14.0) [17]	15.9 (13.3) [19]	-6.22 [-12.60 to 0.16]; Std. effect: -0.54 [-1.09 to 0.01]
9 months	18.6 (11.4) [16]	13.7 (11.0) [21]	-9.55 [-15.91 to -3.19]; Std. effect: -0.83 [-1.38 to -0.28]
DASS-21 Total Stress Score, mean (SD) [n]			
Baseline	25.1 (9.6) [19]	29.1 (8.9) [21]	-
3 months	23.4 (12.3) [17]	19.5 (12.7) [19]	-5.29 [-12.57 to 2.00]; Std. effect: -0.56 [-1.34 to 0.21]
9 months	22.4 (10.3) [16]	20.3 (12.4) [21]	-4.53 [-11.79 to 2.74]; Std. effect: -0.48 [-1.26 to 0.29]

Note. [1]SleepWell therapy+usual care versus usual care only: Mean difference estimated from a linear mixed-effects model adjusting for outcome measure at baseline, time and treatment group as fixed effects and participant as a random effect. Standardised effect size = estimated mean difference divided by baseline standard deviation.

Larger effect sizes were observed at 9 months for all three measures: depression (DASS-D adjusted mean difference -7.66, CI -15.09 to -0.22; n = 37; Cohen's *d* =-0.67, CI-1.33 to -0.02), anxiety (DASS-A adjusted mean difference -9.55, CI-15.91 to -3.19; n=37; Cohen's *d*= -0.83, CI -1.38 to -0.28), and paranoia (RGPTS-A adjusted mean difference -5.90, CI-11.11 to -0.69; n = 38; Cohen's *d* =-0.65, -1.22 to -0.08; RGPTS-B adjusted mean difference=-7.73, CI-14.07 to -1.39; n=38; Cohen's *d* =-0.65, -1.19 to -0.12). Although there were small to medium effect size improvements in the CAARMS, the confidence intervals at both time points are wide and cover a range from potentially increasing to decreasing scores. Descriptive statistics for the CAARMS subscale scores are provided in Table 2.6.

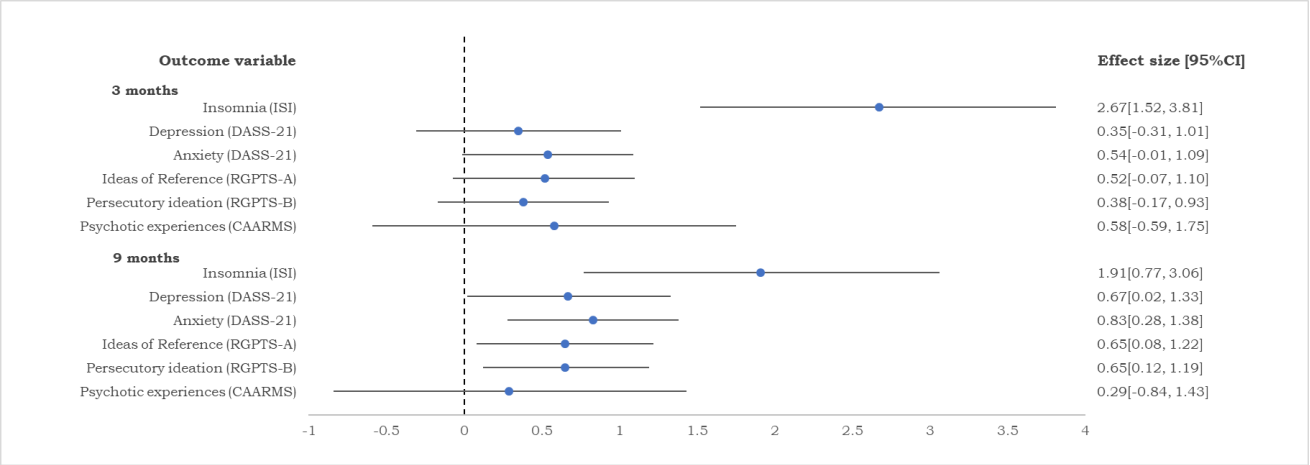

Figure 2.2. Forest plot of effect sizes.

Table 2.6. Descriptive statistics for CAARMS subscale scores.

	Usual care alone (n=19)	SleepWell therapy (n=21)
Unusual Thought Content score, mean (sd) [n]		
Baseline	12.1 (5.5) [19]	9.9 (7.1) [21]
3 months	10.5 (8.5) [16]	10.5 (8.3) [19]
9 months	7.4 (7.7) [18]	9.2 (9.8) [20]
Non-bizarre Ideas score, mean (sd) [n]		
Baseline	10.2 (7.3) [19]	13.1 (6.2) [21]
3 months	11.3 (8.0) [16]	10.8 (7.1) [19]
9 months	10.6 (9.7) [18]	8.8 (8.0) [20]
Perceptual Abnormalities score, mean (sd) [n]		
Baseline	12.5 (3.6) [19]	16.5 (4.5) [21]
3 months	12.3 (7.0) [16]	11.7 (7.8) [19]
9 months	12.4 (9.2) [18]	12.0 (8.0) [20]
Disorganised Speech score, mean (sd) [n]		
Baseline	10.6 (6.3) [19]	11.3 (3.9) [21]
3 months	10.4 (4.2) [16]	9.2 (3.3) [19]
9 months	8.8 (5.1) [18]	8.8 (4.9) [20]

Although not tested, there are indicators of potential differences between groups on secondary clinical outcome measures, for example severity of suicidal ideation measured on the CSSRS, recovery measured on both the QPR and ReQOL, as well as time use measured on the Time Budget. Table 2.7 provides descriptive statistics for the secondary clinical outcome data.

Table 2.7. Descriptive statistics for secondary clinical outcome data.

	Usual care alone (n=19)	SleepWell therapy (n=21)
Sleep variables		
Sleep-50 CRD Subscale Score, mean (SD) [n]		
Baseline	6.8 (2.0) [19]	7.4 (2.3) [21]
3 months	6.9 (2.5) [17]	4.6 (1.7) [19]
9 months	6.4 (2.2) [17]	6.2 (2.5) [21]
Mean total sleep time per night (minutes), mean (SD) [n]		
Baseline	407.1 (124.7) [14]	387.3 (93.0) [15]
3 months	447.3 (119.1) [14]	461.4 (83.2) [12]
9 months	460.8 (54.8) [13]	497.2 (65.3) [13]
Mean sleep onset latency per night (minutes), mean (SD) [n]		
Baseline	68.1 (42.2) [14]	72.0 (61.2) [15]
3 months	60.2 (77.1) [14]	36.7 (27.2) [12]
9 months	36.9 (26.4) [13]	24.8 (16.0) [13]
Mean sleep efficiency[1], mean (SD) [n]		
Baseline	63.7 (16.6) [14]	63.9 (17.0) [14]
3 months	68.6 (24.0) [14]	79.4 (10.5) [11]
9 months	75.8 (9.8) [13]	81.2 (9.4) [12]
Was sleep regularity ≤ 1 hour?[2] n (%) [n]		
Baseline	Yes: 7 (36.8) No: 7 (36.8) [14]	Yes: 7 (33.3) No: 7 (33.3) [14]
3 months	Yes: 6 (31.6) No: 6 (31.6) [12]	Yes: 9 (42.9) No: 3 (14.3) [12]
9 months	Yes: 7 (36.8) No: 6 (31.6) [13]	Yes: 6 (28.6) No: 7 (33.3) [13]
Was the midpoint sleep time between 2am and 4am? n (%) [n]		
Baseline	Yes: 0 (0) No: 14 (73.7) [14]	Yes: 5 (23.8) No: 9 (42.9) [14]
3 months	Yes: 3 (15.8) No: 9 (47.4) [12]	Yes: 4 (19.0) No: 8 (38.1) [12]
9 months	Yes: 2 (10.5) No: 11 (57.9) [14]	Yes: 3 (14.3) No: 10 (47.6) [14]
Psychiatric symptoms measures		
SPEQ-H Total Score, mean (SD) [n]		
Baseline	23.8 (9.2) [19]	23.8 (9.6) [21]
3 months	18.3 (12.4) [18]	18.8 (12.2) [20]
9 months	16.7 (14.0) [18]	14.6 (10.5) [21]
CEFSA Total Score, mean (SD) [n]		
Baseline	74.0 (31.8) [19]	75.8 (41.2) [21]
3 months	65.6 (38.4) [17]	63.2 (37.0) [19]
9 months	60.7 (41.4) [17]	53.0 (41.2) [21]
CSSRS - Most Severe Suicide Ideation Score, mean (SD) [n]		
Baseline	1.5 (1.7) [19]	2.1 (1.5) [21]
3 months	1.4 (1.9) [16]	1.2 (1.3) [18]
9 months	1.0 (1.6) [16]	0.9 (1.3) [18]
DWQ Total Score, mean (SD) [n]		
Baseline	29.8 (9.7) [19]	34.8 (6.5) [21]
3 months	24.9 (13.5) [17]	25.9 (12.3) [19]
9 months	26.2 (10.7) [17]	21.4 (12.3) [21]

BCSS - Total Negative Score, mean (SD) [n]		
Baseline	12.6 (8.0) [19]	15.2 (5.4) [21]
3 months	10.4 (7.2) [17]	9.5 (6.8) [19]
9 months	9.7 (6.6) [17]	7.9 (6.1) [21]
BCSS - Total Positive Score, mean (SD) [n]		
Baseline	6.7 (4.2) [19]	5.2 (4.2) [21]
3 months	7.9 (5.2) [17]	9.8 (4.5) [19]
9 months	9.1 (6.1) [17]	10.2 (5.6) [21]
Activity, social functioning, and recovery measures		
Time Budget Total Score, mean (SD) [n]		
Baseline	63.2 (19.5) [18]	75.5 (14.3) [21]
3 months	63.3 (20.0) [16]	81.4 (11.3) [19]
9 months	69.7 (17.6) [15]	74.5 (14.0) [18]
WSAS Total Score, mean (SD) [n]		
Baseline	22.4 (9.5) [19]	27.4 (6.0) [21]
3 months	22.4 (13.0) [17]	18.3 (12.0) [19]
9 months	19.8 (9.5) [19]	11.1 (9.2) [20]
O-AS Total Avoidance Score, mean (SD) [n]		
Baseline	2.0 (2.2) [17]	3.0 (2.4) [21]
3 months	2.4 (2.3) [17]	2.2 (2.4) [19]
9 months	1.3 (1.6) [17]	1.1 (1.9) [20]
O-AS Total Distress Score, mean (SD) [n]		
Baseline	35.9 (19.7) [18]	42.8 (23.2) [21]
3 months	35.6 (20.5) [17]	31.2 (23.9) [19]
9 months	30.9 (20.5) [15]	20.4 (19.1) [21]
Mean Daily Step Count, mean (SD) [n]		
Baseline	4823 (3685.0) [16]	6700 (3746.7) [16]
3 months	6169 (1958.2) [11]	5527 (3137.4) [15]
9 months	7649 (4792.1) [13]	7402 (5242.0) [14]
QPR Total Score, mean (SD) [n]		
Baseline	28.2 (13.5) [19]	28.9 (13.5) [21]
3 months	31.2 (13.7) [17]	34.7 (11.6) [19]
9 months	31.9 (11.1) [17]	36.6 (10.7) [21]
ReQoL Total Score, mean (SD) [n]		
Baseline	28.5 (16.3) [19]	20.3 (8.1) [21]
3 months	35.4 (17.4) [16]	39.8 (18.8) [19]
9 months	32.1 (17.2) [17]	44.6 (14.3) [21]
Currently prescribed psychotropic medication, n (%)		
Baseline	7 (36.8)	10 (47.6)
3 months	8 (42.1)	12 (57.1)
9 months	9 (47.4)	12 (57.1)
Mean number of prescribed psychotropics, mean (SD)[n]		
Baseline	1.6 (0.5) [19]	1.3 (0.5) [21]
3 months	1.5 (0.5) [8]	1.3 (0.5) [12]
9 months	1.2 (0.4) [9]	1.4 (0.5) [12]

Note. [1]Calculated as total time spent asleep in a night as a percentage of total amount of time spent in bed. [2]Sleep regularity calculated as the standard deviation of the mean midpoint across the sleep diary.

Over 9 months, six participants had a total of eight adverse events (three in the usual care group, five in the treatment group) and one serious adverse event (treatment group). There was one transition to psychosis, in the usual care group. No adverse events were classified as related to trial treatment or procedures.

2.9 Discussion

In this chapter the first randomised controlled trial of a sleep treatment in young people at ultra-high-risk of psychosis is reported. Overall, the study demonstrates the feasibility of testing this psychological intervention adapted for this population. Recruitment targets were met, despite the additional challenges of the COVID-19 pandemic. Retention was extremely high: all participants provided follow-up data. Uptake and acceptability of the therapy were both very high. There were preliminary indications of clinical benefit. Following a brief, targeted psychological intervention there were large reductions in sleep problems, which were sustained at follow-up. There were also reductions in depression, anxiety, and paranoia, with larger effects observed at follow-up. However, the trial was not powered to determine the clinical effects of the treatment.

2.9.1 Treatment uptake, engagement, and acceptability

The uptake of treatment and attendance at therapy sessions was very high. All but one participant received a prespecified minimum treatment dose. The assessments and therapy were delivered in a hybrid format including both remote and in-person meetings. Although initially a response to the restrictions of the pandemic, treatment uptake and trial retention remained high and it is likely this hybrid approach will match future service delivery models which have the potential to increase the range of options available to patients. Within the treatment protocol, flexibility and patient choice in the timings for sessions was offered – this may be further facilitated by online delivery. Within the treatment, all participants collaboratively developed a maintenance cycle formulation of the sleep problem and received psychoeducation about sleep. The most common active treatment techniques were establishing a sleep window (i.e. the key anchor times for sleep and wakefulness) coupled with creating a wind-down routine to prepare for sleep and a rise-up routine to get active in the morning. These techniques address circadian alignment and hyperarousal. Yet there was variance in the sleep presentations – as seen in other studies of early psychosis (e.g. Dondé et al., 2022; Reeve et al., 2019; Waite et al., 2018). Treatment can likely be further refined

through consideration of the different presentations of sleep difficulties and detailing the necessary associated intervention techniques (Freeman & Waite, 2025; Harvey, 2022). All participants engaged in active practice of the treatment techniques between sessions on at least one occasion, with implementation of techniques reviewed in 80% of sessions. This is consistent with previous qualitative accounts of the therapy, in which young patients described a process of 'trying things out' and valuing the experience (Waite et al., 2018). Overall treatment acceptability, engagement, and uptake was very high.

2.9.2 Preliminary clinical effects

The preliminary clinical effects of the intervention on sleep are consistent with the large effects reported in numerous trials of CBTi. For example, in a meta-analysis of 87 trials of CBTi the effect size reported on the ISI was large (g=0.98) (van Straten et al., 2018). Though there have been fewer studies in adolescents, a meta-analysis of nine RCTs demonstrated similar large effect sizes on global sleep quality (d=0.92) (Blake et al., 2017). Large effects have been consistently demonstrated when treating sleep problems across the spectrum of severity of psychosis (Freeman, Waite, et al., 2015; Sheaves, Freeman, et al., 2018; Sheaves et al., 2019). The effect sizes in the current study are even larger and may be considered encouraging. However, it will be important to further refine the treatment. At the three-month follow-up five participants continued to score in the ISI range indicating subthreshold insomnia (n=3, ISI score 8-14) or clinical insomnia (n=2, ISI score 15-21). At the nine-month follow-up one participant continued to score in the clinical insomnia range. One potential avenue for adaptation is to ensure the materials are suitable for neurodivergent participants. Whilst neurodivergence was not systematically assessed or recorded in the trial, clinical observation and patient feedback (see Chapter 3 for further detail) highlights this as an important consideration. Peer led research highlights the importance of curiosity in making adaptations to therapy for neurodivergent participants, particularly regarding the style of therapy (Stark & Authentistic Research Collective, 2021). More broadly this is recognised as a specific training need within psychological therapies (Cooper et al., 2018). This is an area for future development of this work.

The outcomes in relation to psychotic experiences are encouraging. Especially given the small size of the study. The levels of paranoia in the participant group were comparable to those seen in trials with patients with a diagnosis of psychosis (e.g. gameChange; Freeman et al., 2022). The size of treatment effects on paranoia in the current trial are potentially promising. Treatment effects on

hallucinatory experiences were not directly tested in this study. Nonetheless the descriptive statistics on the SPEQ-H and perceptual abnormalities subscale of the CAARMS may provide indications of possible benefit. Overall, however, the treatment effects measured using the CAARMS are less clear. As the measure covers a range of different experiences it may lose specificity, potentially masking changes. Recent revisions of the CAARMS aim to improve the reporting of specific psychotic experiences by expanding the subscales scored and reported (see https://www.orygen.org.au/Training/Resources/Psychosis/Manuals/CAARMS). This was also the only interviewer-rated measure of psychotic experiences with all others being self-report. In future trials it will also be important to assess the distress rating on the CAARMS as this has been identified as a key outcome from this measure (Wilson et al., 2020).

The effects of CBTi on depression are well recognised (Cunningham & Shapiro, 2018), with the approach recently adapted for adolescents (Orchard et al., 2020). The meta-analysis of adolescent CBTi trials also reported outcomes on depression and anxiety, with larger effects at later follow up (Blake et al., 2017). This is consistent with the results in the current study. Indeed, in the current trial the treatment effects on psychotic experiences, depression, and anxiety were larger at the later follow-up. This is consistent with the theoretical rationale that sleep disruption is a causal factor in the occurrence of these mental health problems, and that affect may mediate the relationship between sleep disturbance and psychotic experiences (e.g. Bagautdinova et al., 2023; Bagrowska et al., 2022; Freeman et al., 2017; Reeve, Emsley, et al., 2018; Zaks et al., 2021). A definitive trial with embedded mediation and moderation tests is now required to determine the wider effects (including preventative effects on psychotic experiences), how it works, and who it might work best for.

2.9.3 Limitations

The main limitation when considering the potential clinical effects is that this feasibility trial was not designed or powered to detect anything but the largest effects on clinical outcomes. There was no active comparison to control for elements of the treatment that might have benefit, such as contact time with a clinician. This design gives an overall indication of the benefit of the approach when added to standard care, but not which elements are necessary or if another treatment might be more effective. Further to this there was considerable variability in the sleep presentations – as such it is unclear which treatment strategies should be employed for each presentation (Freeman

& Waite, 2025), nor the proportion of different presentations within the participant group and how this may have impacted the treatment outcomes.

Notably, there were no specific clinical services for young people at ultra-high-risk at the recruiting sites, thus usual care was limited. Given the drive to increase current service provision for young people at ultra-high-risk (NHS England, 2016) in light of the often-sparse availability of services for this group, identifying brief, effective, implementable treatments is a priority for policy makers. The assessments and therapy were delivered in a hybrid format including both remote and in-person meetings. Although initially a response to the restrictions of the pandemic, treatment uptake and trial retention remained high and it is likely this hybrid approach will match future service delivery models which have the potential to increase the range of options available to patients. Online delivery may further facilitate flexibility and patient choice in timings for sessions. In this trial the treatment was delivered by clinical psychologists, including the thesis author. In future work it will be important to test different models of treatment delivery to ensure any future implementation can be achieved within different healthcare settings. For example, there are new roles within the psychological profession, such as graduate mental health worker or clinical assistant psychologists – which are graduate psychology positions with brief training. It may be possible that a broader range of health professionals, including these graduate psychology roles or peer support workers (people with lived experience of the problem and training on how to use this for therapeutic benefit) may be able to deliver this therapy – giving much greater opportunity for access. There are early indications from implementation work in youth mental health services that such a model may be feasible (Rollinson et al., 2021, 2024).

In line with the focus on subjective experiences of sleep disruption and psychotic experiences, self-report assessments were primarily employed. Actigraphic measurements were used as a marker of activity due to the potential physical health benefits of improved sleep but caution should be noted regarding the precision of actigraphy to determine sleep-wake parameters (Aronica et al., 2025).

The study was conducted in a single centre and the participants will not be representative of all young people at ultra-high-risk or accessing mental health services. This is particularly important given the heterogeneity (Fusar-Poli et al., 2016) and range of clinical trajectories observed in the ultra-high-risk group (Polari et al., 2018, 2021). In addition particular minoritised groups may be at elevated risk due to exposure to additional risk factors – such as discrimination (Oliver et al.,

2024). As such, work to improve the inclusivity of trials testing treatments for psychotic experiences, including in young people at ultra-high-risk of psychosis, is essential (Burkhard et al., 2021).

2.9.4 Future directions

Consistent with trials with patients with diagnosed psychosis, the findings from this trial suggest that psychological therapy may produce large improvements in sleep for young people at ultra-high-risk of psychosis. Given the indicated size of the treatment effects, it is possible that sleep disturbance is even more tractable at the earliest stages of psychosis. There are also promising indications now that improving sleep for patients on the psychosis spectrum results in improvements in other mental health symptoms, including anxiety, depression, and paranoia (Bradley et al., 2018; Freeman, Waite, et al., 2015; Sheaves, Freeman, et al., 2018). Yet the evidence, including this feasibility trial, is limited. A definitive trial to determine the full range of effects of cognitive behaviour therapy for sleep disturbance, particularly on psychotic experiences, is now warranted. Sleeping Better (ISRCTN71800376) is currently underway.

Sleeping Better is two linked multi-centre definitive trials testing this adapted sleep intervention with patients with a diagnosis of psychosis and young patients at ultra-high-risk of psychosis. The trial actively involves people with lived experience. In line with the causal hypothesis set out in this thesis, the trial is designed, and powered, to test the effects of the treatment on the prespecified important secondary outcomes of the intervention: paranoia (measured on the RGPTS; Freeman et al., 2019), depression (measured on the PHQ-9; Kroenke et al., 2001) and cognitive functioning (measured on the MATRICS consensus cognitive battery; Nuechterlein et al., 2008). There will be specific mediation tests, investigating if changes in sleep (measured on the ISI) mediate treatment improvement in the important secondary outcomes (psychotic experiences (measured on the RGPTS), mood (measured on the PHQ-9), or cognitive functioning (measured on the MATRICS). Prespecified moderation tests will investigate if treatment outcomes for sleep difficulties (measured on the ISI) are moderated by initial level of cognitive functioning, age, ethnicity, severity of psychiatric symptoms (measured on the ISI, RGPTS, CAARMS) or level of daytime functioning (measured on the Time Use Survey; Hodgekins et al., 2015).

Sleep treatment has the potential to become a first-line treatment in secondary mental health care services. It is feasible and acceptable to conduct an RCT testing a sleep intervention with young

patients at ultra-high-risk of psychosis. A definitive trial to determine the clinical effects is now needed, and the Sleeping Better trial is underway. Understanding the patient experience (see Chapter 3) of engaging in this type of therapeutic work will be important to elucidate mechanistic insights and to inform implementation.

Chapter Three

Sleep disruption and its psychological treatment in young people at ultra-high-risk of psychosis: a peer methods qualitative evaluation[3].

3. 1. Introduction

3.1.1 The potential importance of treating sleep problems in young people at ultra-high-risk of psychosis

Sleep problems can be successfully treated with cognitive behavioural therapy (CBT) even in the context of other mental health conditions (Hertenstein et al., 2022). And there are potential wider effects on a range of other mental health outcomes (Freeman et al., 2017; Scott et al., 2021). CBT for sleep problems has been successfully adapted for people with diagnosed psychotic conditions such as schizophrenia (Freeman et al., 2015; Sheaves et al., 2018). Given the wider benefits of treating sleep problems, it is also plausible that intervening on sleep before the onset of psychosis might be preventative (Freeman et al., 2017, 2020; Bradley et al., 2018). This is a stance that is consistent both with a network perspective (Borsboom & Cramer, 2013) and a clinical staging model (McGorry et al., 2014) in which common nonspecific factors, which are causally connected within dynamic networks of interacting symptoms, may act as early treatment targets to reduce the likelihood of severe mental health problems. This was the focus of the SleepWell trial – reported in Chapter 2 (Waite et al., 2023).

In the feasibility trial (Chapter 2), 40 young patients (aged 14-25 years old) at ultra-high-risk of psychosis were randomised to receive the eight-session targeted youth-focused psychological treatment (SleepWell) in addition to usual care, or to continue their usual care (the control condition). Compared to usual care, provision of the sleep therapy led to substantial reductions in sleep problems and wider benefits across mental health outcomes (Waite et al., 2023). The treatment was popular: 95% of patients took up the treatment and there were high acceptability

[3] *This chapter has been adapted from the following paper, attached in Appendix 3.1:*

Waite, F., Evans, S., Rebello, A., Sharpe, T., Otaiku, J., Iredale, E., Kabir, T., Černis, E., & Freeman, D. (2025). Sleep disruption and its psychological treatment in young people at risk of psychosis: A peer methods qualitative evaluation. British Journal of Clinical Psychology, 65, 746–761. https://doi.org/10.1111/bjc.70002

scores. There were very large effect size improvements in sleep post treatment (Cohen's *d*= 2.7) which were maintained at the 9 month follow up (*d*=1.9). Provision of the sleep therapy was also associated with medium effect size improvements in anxiety, depression, and paranoia with larger effects observed at the later follow up. In this chapter a peer research approach was used to try to gain an in-depth understanding of the experience of sleep problems and their treatment with the SleepWell therapy.

3.1.2 Peer methods research

Peer research is designed and conducted by people with relevant lived experiences. Involvement can vary in the degree of engagement – from passive to active – throughout each stage of the research process (see figure 3.1; Prebeg et al., 2023). Peer methods can be seen as an important shift towards partnership in the research process (Prebeg et al., 2023). To achieve this consideration must be given to the degree of flexibility (different types of involvement), fluidity (movement between roles in a research project), and relational empowerment (degree to which power is shared within the research team and process) in the research process (Preberg et al., 2023).

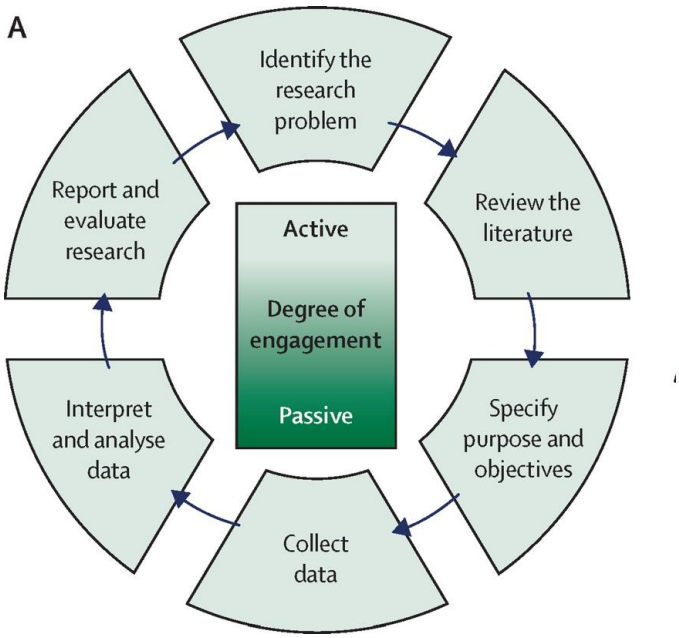

Figure 3.1. Degree of engagement in a responsive methodology of patient engagement in youth mental health research (Preberg et al., 2023).

Employing peer methods has the potential to facilitate more nuanced and rich data collection and analysis by enhancing rapport (Terry & Cardwell, 2016) and levelling power (Harding et al., 2010). This collaborative approach, including researchers with different perspectives and expertise,

including lived experiences, can strengthen the validity and trustworthiness of qualitative methods (Gillard et al., 2010; Sweeney et al., 2013). Accounts from peer-researchers with lived experience of being at ultra-high-risk of psychosis indicate the value of participatory research for the peer (Trimmel et al., 2024). In particular that peer research can foster a sense of community and connection between researchers and give a sense of meaningful achievement (Trimmel et al., 2024).

3.1.3 This chapter

Reflexive thematic analysis (RTA; Braun & Clark, 2021) is an interpretative approach to qualitative data analysis that facilitates the identification of themes (recurring concepts or ideas) in the data and explicitly acknowledges and emphasises the active role of the researcher in the interpretation. This approach complements peer methods and enables a combination of peer and non-peer perspectives. In this chapter, a peer-methods qualitative study, employing RTA, was conducted to explore SleepWell trial participants' experiences of sleep problems and their treatment.

3. 2. Methods

3.2.1 Study design

The study received ethical approval from the Health Research Authority (HRA/HRCW: IRAS 281235, The SleepWell trial) and NHS South Central – Oxford A Research Ethics Committee (20/SC/0281) as part of the SleepWell trial (appendices 2.2-2.4). Criteria to promote credibility in qualitative research were used to inform the design and conduct of the study (Tong et al., 2007).

3.2.3 Peer-methods

This was a peer-methods qualitative study. As such the study was designed, conducted, and analysed in collaboration with people with relevant lived experience. This included three peer researchers from the SleepWell Lived Experience Advisory Panel (LEAP). The SleepWell LEAP is a group of four people with lived experience of sleep problems and psychotic like experiences. The LEAP was facilitated by the McPin Foundation (www.mcpin.org), a charity that exists to put the lived experience of people with mental health problems at the heart of research.

In line with guidance set out by Preberg and colleagues (2023), there was a degree of flexibility (i.e. there were different types of involvement opportunities and roles: advisory panel, data collection,

data analysis, authorship) and fluidity (i.e. the opportunity and support to facilitate movement between roles: training on data collection and analysis) in the peer methods. There was also an active effort and attention given to the degree to which power was shared within the research team and process (relational empowerment).

The LEAP were involved in all aspects of the study – from design to authorship. LEAP members were then invited to take on additional roles as peer researchers – this could be in the data collection or data analysis (i.e. flexibility). The invitation and outline for the peer co-facilitator role is included in appendix 3.1. The co-facilitator role involved conducting approximately eight interviews – each lasting approximately one hour. The peer was invited to draw on their lived experience – for example informing the participant of their relevant lived experience. The role was paid. It was made clear that the peer researcher would not be expected to undertake administrative work for the interviews (e.g. process participant payments, organise transcription and secure data transfer), nor to manage any risk information that was disclosed during the interview. The peer co-analyst role involved completing analysis on transcripts from the interviews. The role was paid. The time for analysis of a transcript can vary however it is expected to take several hours for a single interview (Braun & Clark, 2021) – this is typically longer for those who have less experience and may also be longer for those who are connecting with the data due to similar lived experience. Therefore, peer researchers were invited to complete full analysis of a single transcript in the first instance.

Training was provided (to support fluidity). The training included: 1) understanding the role and responsibilities of the peer research role; 2) learning how to draw on lived experience (what, how, and when to share information); 3) understanding how to work collaboratively with other members of the research team (what to expect from the other researcher in the interview/analysis and as part of the wider process); 4) conducting the interview (including completion of role play practise interviews) or analysis (including understanding the RTA six-step process – see section 3.4); and importantly 5) developing a 'working well together action plan' – see appendix 3.2 for a template. The wellbeing plan is an advance agreement on how best to support the peer researcher throughout the research process. It is a live document that is reviewed regularly.

Attention was given to relational empowerment - the degree to which power was shared within the research team and throughout the research process. For example, in the conduct of the interviews, through the reflexive journalling (individually and shared between interview facilitators), and the generation of the thematic map in the analytic process. Decisions were made

in collaboration and consultation with all lived experience advisors and all are co-authors of the resulting work.

Below is a quote from one of the LEAP members about their experiencing of being involved in the project:

> *"As an individual who has sat on the other side of the table, I feel a sense of ownership both on the LEAP and Co-researching position. It's so refreshing to see its positive impact on others which has really boosted my own confidence. The SleepWell team are non-judgemental, very supportive, and have a clear passion for improving mental health care. The relationship between health care professional and lived experience professional has a clear objective which is to work as a singular unit to produce an efficient and proactive work plan to support those in need. It has a fantastic work culture and I am proud to be involved. I feel that my input is respected, and utilised or adapted where suitable. I feel comfortable working with the team without worry of being rejected, no answer is wrong and every suggestion is considered. I have and continue to enjoy every moment working with you and the team"*

3.2.4 Research team – positionality statement

People with lived experience of sleep problems and psychotic-like experiences were involved in all stages of the study. The research team included three peer researchers who have had similar experiences to those being explored (one conducted data collection, one conducted data analysis, and one conducted both data collection and analysis) and clinical psychologists who developed the sleep therapy. Working with the LEAP there was a commitment to embed peer knowledge in the design, procedure, and presentation of findings.

3.2.2 Reflexive Thematic Analysis

Reflexive Thematic Analysis (RTA; Braun & Clark, 2021) was used to analyse the data. This analytic method is used to identify and infer patterns of meaning across a dataset. A critical realist approach was taken based on the assumption that any objective reality is observed through the unique lens of the researcher. Therefore, this method can accommodate combining peer and non-peer researcher perspectives. It also allows for unexpected discoveries (Braun and Clarke, 2006) – which is important as this was the first peer-methods qualitative study on this topic.

3.2.2.1 Ontology and epistemology

This study adopts a critical realist ontological position. Within this position, critical realism is understood to indicate that reality has an independent existence which is accessible only through the filters of culture and language. Contextual epistemology adds the position that an individual cannot be separated from the context in which they exist and operate (Braun and Clarke, 2021b). In short, in this position it is understood that an independent reality exists, but it is only ever understood from the particular lens of experience of an individual in their particular context. These assumptions position the participants as the interpreters of the realities of taking part in the SleepWell trial, and where applicable therapy, within the context of help-seeking for sleep disruption and psychotic-like experiences. The research team are then the interpreters of the data and bring expertise from lived experience, research training, and clinical experience.

3.2.3 Participants

Participants had taken part in the SleepWell trial – see Chapter 2 (ISRCTN85601537; Waite et al., 2023). The participants were young people (aged 14-25 years) attending NHS mental health services with sleep problems who are at ultra-high-risk of psychosis (assessed on the Comprehensive Assessment of At Risk Mental States (CAARMS) (Yung et al., 2005). The inclusion and exclusion criteria for the trial are listed in the trial protocol (Waite, Kabir, et al., 2020) – appendix 1.1. The additional criteria for this qualitative study were: willing and able to give informed consent and willing to have the interview audio recorded and for the use of pseudonymised verbatim quotes.

3.2.3.1 Recruitment methodology

Criterion-based purposive sampling was used to maximise variation in participant characteristics including uptake of therapy, age, gender, and ethnicity. Participants were invited to take part in the qualitative study after their final follow-up assessment in the trial (9 months after the baseline assessment). The principle of maximum variation in the participant group was sought to try to include a wide range of experiences in relation to the therapy and trial (Palinkas et al., 2015), for example, different uptake of therapy and a range of therapy delivery methods (online or in-person). To achieve this, initially a consecutive cohort of participants were invited. Further variation was then sought. However the high uptake of therapy (all but one participant received the pre-specified treatment dose) limited some of the proposed variation.

The planned number of participants was 16 (ten participants who had been randomised to the therapy in addition to usual care group and six from the usual care alone group i.e. were in the

treatment as ususal only control group). The principle of 'information power' – which refers to the extent the characteristics of the study enable the research question to be answered (Malterud et al., 2016) – rather than 'saturation' – the point at which no new themes are generated from the data - was applied. Therefore the size of the participant group is derived by considering the specific aim of the research, the theoretical framework being applied, the quality of the interview dialogue, and the analysis (Malterud et al., 2016). Within this study the aim was broad indicating the need for a larger participant group, yet the quality of the interview dialogue was enhanced by the use of peer methods suggesting higher information power and therefore requirement of a smaller number of participants. The participant group was therefore estimated at the outset of the study and revisited during recruitment to ensure sufficient information power to answer the research question. Seventeen people were invited to participate, one declined, 16 consented. Written informed consent, including consent to the use of pseudonymised quotes, was obtained from all participants.

3. 3 Procedures

3.3.1 Interview guide

The semi-structured interview guide was developed with reference to existing literature, guidelines for good practice, and in collaboration with the LEAP. It was further refined following pilot interviews with the LEAP. There were three main topics: the participants' experiences of sleep problems; any changes in sleep over the period of trial participation; the experience of taking part in the study; and, if applicable, the experience of the sleep therapy. Following guidance from the LEAP, the interview guide was provided to participants before the interview (appendix 3.3). During the interview it was used flexibly to focus on the participants' narratives and allow for the exploration of new ideas. Tailored prompts were used to elicit further detail, clarify points, and refocus if needed. The participants' own language was used whenever possible. All four interviewers had received training in interview methods, and each practised the interview in a series of pilots.

3.3.1 Interview process

Interviews were conducted remotely (in line with COVID-19 restrictions) between February 2022 and January 2023. Each interview was facilitated by one peer researcher (nine by one researcher and seven by another) and one clinical psychologist researcher (12 were conducted by the thesis

author and four by another psychologist). At the start of the interview, the researcher and peer researcher introduced themselves, their expertise, and relevant experience. After this the peer researcher chose when, how, and what to share with the participant about their potentially related experiences. This differed between interviews. For six participants the clinical researcher facilitating the interview delivered the sleep therapy. The peer researchers were not known to any participant. Consideration was given to the relationship of the researcher to the participant – both for the peer and the psychologist - given the conceivable importance of this in qualitative research (Ritchie et al., 2014). Interviews were conducted in a single session, the duration was between 17-68 minutes (mean=42 minutes, SD=17 minutes). Brief field notes were taken. Interviews were audio-recorded, transcribed verbatim, and deidentified.

3.4 Analysis

The six-phase process outlined by Braun and Clarke (2006, 2021) was followed. This included: 1) Familiarisation with the data; 2) Generating initial codes – both semantic and latent; 3) Generating themes; 4) Reviewing potential themes for coherence, meaning, and robustness, 5) Defining and naming themes; and 6) Producing the report. Throughout the analysis specific consideration was given and efforts made to incorporate the range of ways people communicate and articulate themselves during qualitative research (Gupta et al., 2024). Extracts of the initial coding and generation of themes (informed by Byrne, 2022) are provided in the appendix (appendix 3.4 and 3.5).

The analysis was completed by multiple coders, all trained in data analysis, including two peer researchers. This was undertaken in a collaborative, reflexive approach with the aim of achieving richer interpretations of meaning, rather than seeking consensus. The analysis was an iterative process with themes discussed with the LEAP and co-authors to consider the most appropriate way to convey the participants' experiences. Five LEAP meetings were held as part of the analysis. Examples of this iterative process are listed below. Firstly, the initial thematic map was revised as part of a presentation of the preliminary results in preparation for a LEAP (see appendix 3.6). Secondly, the LEAP meetings resulted in a number of revisions. For example, setting the context of the sleep therapy within the challenging journey to access support was important to the LEAP and is therefore presented as the first theme to provide the reader with this perspective. Thirdly, discussions within supervision and with other members of the research team helped to distil the key learning and condense the main findings. Finally, the process of naming the themes was

iterative – initially the titles were too opaque and insufficiently embedded in the data. Revisions ensured the titles were sufficiently descriptive and acted as 'mini-mini abstracts' that provide a headline for the story of that theme (Braun & Clarke, 2022).

398 references were coded. These initial codes were organised into three themes which shared common ideas. The themes were reviewed, reconceptualised, and re-labelled to produce the final four themes and three subthemes reported.

3.4.1 Rigour

To support the clarity and cohesion of the methods with the underpinning philosophical stance of the study consideration was given to reflexivity and credibility. This included the use of guidelines and checklists for conducting the analysis/study (Braun and Clark, 2021; 2022) and reporting the research (COREQ, Tong et al., 2007). Methods to support reflexivity included a bracketing interview, reflexive log, and reflections – individually and jointly – after each interview. The construction and interpretation of the coding and themes were discussed and refined with the LEAP and co-authors to invite different perspectives.

3.4.1.1 Reflexivity

Reflexivity involves the researcher identifying their own position, assumptions, and values in relation to the study. It is a process of reflecting on how decisions and interpretations are reached, from the design of the study to the final reporting of outcomes (Guillemin and Gillam, 2004). It is a crucial component in reflexive thematic analysis to ensure the rigour of the study design, conduct (data collection and analysis), and reporting (Braun and Clarke, 2021).

Prior to data collection bracketing interviews were conducted to help understand the positionality of the team. The interviewers each maintained a reflexive log throughout the data collection process and had a brief period of joint reflection after each interview to note key learning, draw on the two perspectives, and identify any oversights. The journaling process helped to identify assumptions and responses that might limit or shape the interpretation of the data, for example: the *values* related to respecting others, the *assumptions* regarding the potential benefit of a psychological therapy approach, and the cultural *norms* regarding mental health problems, help-seeking, and stigma. It also provided an opportunity to note the emotional responses to the participants and the data collected – an important part of supporting peer researchers. Further

entries were made during the analysis of each transcript, after LEAP meetings, and discussions with other members of the research team.

3.4.1.2 Checklist for good practice

The 15-point checklist for good practice in RTA (Table 3.1) was used to support a reflexive, rigorous, and systematic approach (for a detailed example see Braun & Clarke, 2024). It was designed to 'foster depth of engagement, researcher reflexivity, and theoretical knowingness' (Braun & Clarke, 2021; p.267).

Table 3.1. 15-point checklist for good practice in Reflexive Thematic Analysis.

Process	No.	Strategies undertaken
Transcription	1	The data were transcribed verbatim, checked for accuracy against the audio recordings by the transcriber, and two researchers.
Coding and theme development	2	Each transcript, code, and proposed theme was reviewed repeatedly in an iterative process. Reflections regarding the reactions, emotional responses, and meaning of each section of data were noted in the reflexive log.
	3	Thorough, inclusive, and comprehensive consideration was given to each transcript, with awareness of the range of ways people communicate (i.e. caution regarding excessive reliance or influence of articulate and vivid examples). A curious stance was adopted involving an assumption that the researcher required an active reflection to seek to understand the participants' experiences.
	4	All relevant extracts for each theme were collated and reviewed during a LEAP meeting.
	5	Candidate themes were checked against coded data, the original dataset, and for coherence with peer researchers and other members of the research team. Themes were revised at each stage.
	6	Each theme was reviewed by the LEAP, supervisor, and wider research team to ensure internal coherence, consistency, and distinction. Each theme is organised around a central concept with sub themes used judiciously to provide nuance that was particularly meaningful to participants (Theme 2), and to reflect the dynamic interaction of two positions within a central concept (Theme 3).
Analysis and interpretation	7	Data have been analysed and interpreted using peer methods. This includes data collection and direct coding of transcripts, as well as discussions in response to presentations of potential themes and example data extracts. The theme titles reflect the analytic process: they provide the active interpretation of the data by the research team as to what is meaningful to participants.
	8	There is consistency between the analysis and data, with extracts used to evidence the analytic claims, with further emphasis noted when the analysis resonated with particular components of the peer researchers' lived experiences. All participants provide extracts in the written report and their contribution across themes is summarised in Table 3.2.
	9	The analysis addresses the aims of the research and provides a narrative of participants' experiences related to the participating in the SleepWell trial and therapy, in the context of seeking help for sleep disruption and other mental health problems. The overall narrative was clarified through discussions with supervisors and presentations to the LEAP.
	10	Both analytic narratives and data extracts are provided. A reflexive journal was maintained throughout the research process to identify the values, assumptions, and norms in which the research team are embedded. This reflective process captures part of the process of shaping the analytic narrative.
Overall	11	Throughout the analysis extensive time was invested by peer researchers and the lead researcher to consider each transcript individually, the data as a whole, and to revisit each transcript in an iterative process incorporating discussion with other researchers and the LEAP.
Written report	12	The theoretical position and assumptions are clearly stated. The approach to the analysis is detailed, including the use of peer methods.
	13	The method and analysis are consistent with the approach., including the critical realist and contextual epistemological position.
	14	The language and concepts used in the report are consistent with the critical realist ontological and contextual epistemological positions of the analysis.
	15	All researchers were active in the research process and are positioned as such in the report.

3.5 Results

3.5.1 Contextualising the findings

16 people took part. The average age was 18 years old (SD=2, range 15-22). Eight participants identified as male, seven as female, and one as other. Most participants were White (n=13), two participants were Asian, and one was mixed heritage. Ten participants had received the SleepWell intervention (expected to be delivered in around 8 sessions, with a treatment dose defined as at least four sessions). The mean number of therapy sessions attended was 8.7 (SD=1.9, range 6-12). All participants had experienced sleep problems. Assessed using the Insomnia Severity Index (ISI) the mean score for all 16 participants at the start of their participation in the trial was in the moderate insomnia range (mean=17.8, SD=1.9, range 11-23). For the ten participants who received the intervention the mean baseline score was 18.8 (SD= 3.16, range 12-23). At the 9-month follow-up assessment (conducted approximately 6 weeks before the interview), the mean score for the ten participants who had received therapy was below the clinical cut off for insomnia on the ISI (mean=6.5, SD=5.4, 0-17). For the six participants who did not receive the intervention the mean score on the ISI was 16.1 (SD= 3.43, range 11-21) at baseline and 11.8 (SD=6.6, range 6-20) at the 9-month follow up assessment. The participant characteristics in this qualitative study, including changes to sleep problems post treatment, are consistent with those seen in the main trial across the whole patient group (see Chapter 2; Waite et al., 2023).

3.5.2 Overview of findings

Four themes were generated: 1) The challenge to access mental health treatment ('Bouncing between services'); 2) Sleep problems and mental health difficulties are intertwined ('An obvious link'); 3) Flexibility in therapy provision matters ('Tailored to me as a person'); 4) Improving sleep leads to wider benefits ('Fixing the sleep helped everything else'). Participants described being overlooked and finding it hard to obtain help – for sleep problems as well as other mental health difficulties. This left patients with a sense of isolation, frustration, and hopelessness. Participants described being engulfed in a loop of co-occurring sleep disruption and mental health struggles. Flexibility in the delivery of the treatment enabled participants to actively, and effortfully, make progress and take ownership of the changes and the process. There were many benefits beyond better sleep: fewer voices and fears, improved confidence, reduced suicidal thoughts, greater connection with others, attendance at work and college, and engagement with everyday life. The

pattern of participant contribution to the themes is shown in Table 3.2. Additional illustrative quotes are provided in Table 3.3.

Table 3.2. Summary of participant contributions to each themes.

Themes	Participants															
	1	*2*	3	*4*	*5*	6	7	8	9	*10*	11	*12*	*13*	14	15	16
1) The challenge to access mental health treatment: "Bouncing between services"			X			X	X	X	X	X	X		X	X	X	X
2) Sleep problems and mental health difficulties are intertwined: "An obvious link"	X	X	X		X	X	X	X	X	X	X	X	X	X	X	X
Bidirectional interaction between sleep problems and psychotic experiences	X		X			X		X		X					X	X
3) Flexibility in therapy delivery and provision matters: "Tailored to me as a person"	X	X	X	X		X	X	X	X	X	X	X	X	X	X	X
Flexibility and rhetoric matter	X	x	X	X		X		X	X	X	X			X	X	
Active engagement and ownership: making the most of therapy	X		X			X	X	X			X	X	X	X	X	
4) Improving sleep leads to wider benefits: "Fixing the sleep helped everything else"	X		X			X	X	X	X	X	X			X	X	X

Note. Italicised participant numbers (2, 4, 5, 10, 12, and 13) did not receive therapy within the trial

3.5.3 Theme 1: The challenge to access mental health treatment: "Bouncing between services"

Participants described the repeated challenges of accessing help – for sleep problems as well as other mental health difficulties: *"Obviously, people like me, obviously have gone through the cracks, a lot"* (P3). They described being overlooked and finding it hard to obtain help. The language participants used was striking: *"*laid off*"* (P6), "abandoned" (P14), "ignored" (P11), "didn't want me" (P3). There was a clear sense of rejection and frustration:

> *Yeah, so uh, when I went into services, they kind of just, swiped me under the rug and said 'You know look, we deal with people who are upset or anxious or, kind of this' and they literally said to me 'You're too much of a problem for us with us with all of the stuff that you're doing to yourself and all the stuff that you're going through so what we're going to do is, we are going to treat it nowhere near as seriously as it should've been' uhm, and you know for me back then, it kind of hit a bit. P6*

Here P6 describes their experience of being ignored, invalidated, and uncontained as they sought help from mental health services. There is repetition throughout the interview of key phrases, for example: "*I'm gonna be honest, they weren't very good with me. They kind of, they kind of laid me off and said I was too much of a problem for them to deal with."* As with many participants, this knocked the participants'

confidence in services and in themselves – making it harder to continue the journey to accessing help.

Referral to participate in the SleepWell trial was often unexpected as described here by P3:

> *I had a very big issue, obviously, the mental health services didn't really want me because I don't fit their criteria, and obviously I was supposed to wait for another programme to open. I don't even know if the other programme's opened because no one's contacted me about it. So, I just kind of needed something because I wasn't in a good head space, so it was a bit… Uh, to be fair, when I first got told about SleepWell, I thought, 'That's quite a strange thing to stick me on, considering,' but I was okay, but what can I… But I can't lose anything. P3*

As can be seen in this account, these challenges left patients with a sense of isolation and resignation at the start of therapy, rather than hope or expectation. With participants using phrases such as: "nothing to lose" (P9), "worth a shot" (P11), "may as well" (P13), "this could be a big waste of time" (P3), "try anything" (P16).

The LEAP flagged the potential longer-term consequences of not intervening at this key time of mental health deterioration which often occurs during an important developmental life stage. They highlighted the potential benefit of a brief sleep intervention: "it could make all the difference for those on the edge" and identified opportunities to embed this approach within the treatment pathway between primary and secondary mental health services. This suggestion was consistent with participant accounts in which the sleep treatment was considered a first step, a route to build trust and confidence in services.

3.5.4 Theme 2: Sleep problems and mental health difficulties are intertwined: "An obvious link'

Participants described the interaction between sleep disruption and mental health difficulties as "obvious" (P11). Noting with confidence, for example: "100% definitely, definitely, definitely" (P6), that sleep problems, anxiety, depression, and psychotic-like experiences were "intertwined" (P10). The consequences of the spiralling sleep problems and other mental health difficulties were significant: knocking participants' confidence and energy to engage in everyday life, with the LEAP members noting how this often led to isolation which bought further negative impacts on mental health.

Further to this, participants spoke of the complexity of the sleep disruption itself. Sleep was unpredictable. Sometimes there was too much sleep, sometimes too little, and at other times no sleep at all:

> *So, in the day, I was just so overwhelmed and anxious by everything, that all I wanted to do was just sleep. But then, sometimes, it would be the opposite. I would be so anxious and worked up that I just can't sleep at all, or I will go to sleep and wake up anxious. Go back to sleep, wake up anxious and in a cycle. So, it's not always that I can't sleep but sometimes I think I just want to sleep all the time if I'm particularly anxious, which then, I guess, if I'm sleeping in the day because I'm anxious, then at night you can't sleep because I've slept all day. P13*

3.5.4.1 Sub theme: Bidirectional interaction between sleep problems and psychotic experiences

A bidirectional relationship was described between psychotic experiences and sleep problems: sleep disruption could both cause voices and fears and result from those psychotic experiences.

> *So, if I hadn't slept well, I would end up hearing things a bit more, end up seeing things a bit more and it ended up just really, being worse off without sleep. I think it's something to do with the fact … like I said before, your brain gets overworked, and it starts to like … in terms of computer terms, it starts to malfunction, and it would start to, like, deteriorate a little bit. Then when you sleep, it starts to repair itself. It's like fixing a computer with viruses in it. When it shuts down and it sleeps, it works … it starts to work very well the next day. And I think of the brain like that, as in it's like a computer. As in, it has to shut down, reboot and then it can start doing its daily process. P10*

> *It was definitely the shadowy figures and those voices that got in the way of sleep, because it just made me anxious. So, I stayed awake for a long time, just so I could calm down. I used to go on games and distract myself instead of having to look at myself. It was tiring. I had like low confidence, low mood and low self-esteem, and during the day I was tired, and it meant I couldn't function properly. P9*

For those participants who described being wary and suspicious of others, disrupted sleep made it even harder to trust: "*I'm exhausted maybe I don't want to see any good in someone, so that will make me less likely to trust them."* (P16) and these concerns often played on their mind at night, making it harder to sleep.

For many participants the interplay of sleep disruption and mental health difficulties was experienced as overwhelming and inescapable. With the interaction described as "leading me down a hole" (P6), a "downward spiral" (P16), a "negative loop" (P6, P9) or "cycle" (P13) that "engulfed" (P8) and "trapped" (P14) participants. The LEAP members reflected how this was consistent with their experiences, as one member put it: "both the spiral down and recovery can be defined by how you are sleeping".

3.5.5 Theme 3: Flexibility in therapy delivery and provision matters: 'Tailored to me as a person'

Throughout the participant accounts the importance of personalisation was clear. The specific style of the therapy – characterized by a collaborative, focused, tailored approach – allowed patients to feel heard, validated, and empowered to take action and then create a sense of self-ownership of the progress made. Two subthemes are reported that highlight the dynamic interaction between a) the therapy style, content, and deliverer, and b) the active, effortful engagement by the patient.

3.5.5.1 Sub theme: Flexibility and rhetoric matter

As reported in Theme 2, participants reported many interacting difficulties that felt overwhelming and unstoppable. In contrast, the therapy had a clear target: improving sleep. This provided focus amidst complexity. The clear aims of the therapy were reflected in the name of the approach, 'SleepWell'. The "straightforward and transparent" (P8) language helped foster trust. The rhetoric, as termed by the LEAP, of the approach was important for promoting hope, and an understanding of what was expected in this active approach: "Not talking about stuff, actually doing stuff". (P1).

Choice, tailoring, and personalisation were seen as embedded in the approach, and were highly valued. The selection and application of techniques was experienced as individualised: "it was very tailored to me as a person" (P6). With further recognition that it was personalised for all: *"I genuinely felt like every single person that was a part of this was cared for and thought of and every single case had been adapted to fit that person." (P14).* Yet at times personalisation required contrasting styles of treatment delivery. For example, one participant noted that for neurodivergent participants flexibility meant consistency of sessions and reducing the social demands of the sessions: "*Just about flexibility around a person's different issues, like disabilities or mental illness and stuff. Like, if they have Autism, maybe slow down and let the person think more, rather than being quick … it was difficult for people like me, how to react and how*

to plan in advance for sessions. … I think it's good because being active in therapy [it] helps you talk better and let things out" (P9). Therefore, there was choice in the practicalities of sessions for example the location, modality (online or in person, remaining within the therapy room or taking a walk during the session), timing, and use of materials. Prompts and communication between sessions supported people to try out the techniques: "*they were good with communication, with like emails and text messages to help remind me, so they definitely helped with the reminders of things"* (P16).

Accessible explanations of the techniques and tailored rationales for their use boosted uptake, for example: *"I found it quite easy to follow. They kind of adapted to my situation, they were very good at that. So, most of the tasks was easy to complete." (P16).* The clarity of explanations given in the therapy was a recurring topic in the accounts:

> *It was explained a lot more clearly, a lot more in-depth and they allowed me to understand what this technique should be able to do. And it really explained to me that this technique could be really helpful. It really mattered to me because it allowed me to get more information on the technique and more, like, more efficacy out of it. And it really helped me with understanding how to do the technique and how it should work and so on. P10*

Individuals often described the powerful gains made from specific techniques and shared their understanding of how they might work, for example the wind-down routine was described as: *"having that time to cool down gave my brain a bit of quietness to fully chill out." (P8).* Regular measurement of key outcomes – shared using summary graphs in sessions - provided a "massive eye opener" (P14). There was a spirit of curiosity and experimentation with the therapy techniques – working collaboratively to discover how a strategy might work best for the individual: "*This was very tailored to me as a person, y'know if that didn't work, then y'know, this might and I'd try it and go 'ah yeah it worked!' Or 'it didn't ' and it would be very self-orient – self-oriented from me which I thought was amazing as well." (P6).* Some participants were able to recount with great detail the strategies they had learned and implemented – demonstrating their new found expertise:

> *Putting a routine in place and having that sort of wind-down time. Having a time to cut off from things that I was doing, or interesting things. To have that time to wind down and to chill out. And then, to sort of … in chunks of time, limited time I suppose … to get to sleep really. So, there was, you know, forty-five minutes of chill out. Then, after that, it was thirty minutes of in bed, just chilling and then you*

would eventually fall asleep. So, that is what I think … one technique that stuck with me. It's implementing a routine really, and how much that helps. P8

The focus, language, and tailored techniques were provided in the context of a therapeutic stance in which participants described feeling heard, understood, remembered, and therefore cared for:

Remembering about the people you're talking to definitely made me feel more comfortable because I felt listened to and acknowledged. And for me, the ability to see progress was great. Not just in myself but see it on paper; in graphs and reports that had been built up over the many weeks. To see that result was very, very positive for me to physically look in front of me and go, "cool, here is the actual black and white of how I felt and then this is now". That was really positive. And having the ability to work on it yourself and fill out things, your own personal experience. And then work on that in sessions was great. P8

This extract reflects the specific features of the style, content, and delivery of the therapy which were important to participants. One suggestion to further improve the flexibility in treatment provision was the involvement of people with similar lived experiences in the delivery of the therapy:

I think … well, for me, I would want someone who's been in there with sleep issues. Like, whether that be another participant of the SleepWell clinic or whether it be someone else who has had the sleep therapy, so that we can sort of not only connect with each other… like connect with the therapist a little bit. P10

For some the end of therapy was experienced as abrupt, it 'suddenly stopped' (P9), for others it 'gradually fizzled out' (P1). Some participants described a sense of loss following a meaningful therapeutic connection and long fought for support. Sometimes it was hard to sustain change after the regular sessions finished: 'so I started to slip up' (P9). Others noted a mix – both satisfaction and nerves at the end of therapy – reflecting the important dynamic of collaboration in therapy and independently driving and owning progress: '*so I think ending it was … it was nice to know that there had been an end point that had reached, and a result was there, but still a little bit anxious to be on my own with it and not have that person to, like, talk to and discuss about the issues, I suppose.' (P8).*

3.5.5.2 Sub theme: Active engagement and ownership: making the most of therapy

Participants described their active effortful approach to the therapy with a sense of ownership: "I did the hard work" (P3), "I put the effort in" (P6). Participants were eager to prepare, learn, and make the most of the sessions. The therapy materials facilitated a process of discovery – gaining new knowledge and insights. There was an impressive level of detail in the description of specific techniques. One participant described using their new expertise to support their friends to also achieve better sleep. The refreshing, practical, interesting therapy was hard work, yet enjoyable. In the extract below the participant describes how they became increasingly self-reliant as they now had the necessary skills and knowledge to improve their sleep, and wider day-to-day life:

> *I don't know how to explain it … it was nice to be able to rely on myself to do the routines and everything else. So yeah, it was just very nice to be able to rely on myself instead of everybody else to tell me how to do it. It was relieving that I now had the solution to my problem. P11*

Despite the challenging journey to access help and the sense of resignation described in Theme 1, participants became actively committed and engaged in the therapy, finding a "willingness and wantingness to do it." (P16) as they became self-reliant and able to successfully apply their learning over the longer term, as it became "just quite normal now" (P7). This recognition of the effortful engagement and responsibility for change was clear in the accounts:

> *I always, like, pushed myself to attend. Um. I dunno, the biggest thing is, obviously, no one else is gonna change or help you other than, really, you. Like, you can have the tools and stuff, and the therapist and people that are there that really want help, but, like, you're not going to get any better if you're not trying yourself. P3*

The flexibility, rhetoric, and individualisation of the therapeutic approach was highly valued by all participants in the study. There were also clear descriptions from interviewees who did not receive the therapy of similar helpful features of how the trial was conducted such as: the choice and options that were actively provided throughout the consent, randomisation, and assessment procedures as well as the active efforts to demonstrate the values of the approach – such as respecting and valuing the individual:

> *There was no miscommunication, which commonly happens. But I think you guys were so good at making sure of what I was saying, like, you would double check what I was saying and then if you didn't understand you would ask me to explain again. And I think that's really good, 'cause some people just like… leave it. P2*

3.5.5 Theme 4: Improving sleep leads to wider benefits; "Fixing the sleep helped everything else"

The final theme reflects the meaningful changes participants described as a result of the intervention and the resulting improvement in sleep This included both the scale of the change, often described as life-changing, and the breadth of the "knock on benefits" (P6; P8) as described in the account below:

> *One of the things that was rough before was sleep and I think that's sort of had a knock-on effect with sort of everything else to do with my mental health. But the sleep, since being in the trial, has improved drastically and it's sort of, again, I've said it had a knock-on, in a positive way to sort of stabilise everything, P8*

The changes were also said to be noticeable to others. In the extract below the impact on social relationships is clear. Further to this the participant describes the importance of sleep as a route to 'normality'. An important contrast to the sense of things being odd and overwhelming that was described in Themes 1 and 2.

> *Once I started to sleep better, and sleep throughout the night, then I had more energy to do things that I wanted to do. I could go out and see my friends and I wouldn't feel exhausted all the time. And I could actually be a part of what was around me, instead of just feeling like I could … just like walking through fog. That's almost what it felt like when I wasn't sleeping properly. Whereas now I just feel like a normal human being. So, that's a relief. I definitely felt happier, and I think I was worrying a little bit less because I was able to be a part of what was going on around me. I wasn't just stuck in my own head. So, I was actually listening to what people were saying and actually being able to be involved in conversations fully. P11*

Participants used similar evocative phrases when describing the scale of the changes, such as "transformative" (P3, P14), "massive difference" (P16) and "it changed my life" (P2, P10, P14). Participants particularly noted their surprise at the amount of change achieved in such a short time frame, and when taking a specific focus on just one of the many challenges they were facing: sleep disruption. The sense of transformation was often linked to the wide range of benefits that participants had noted:

> *it's just been a snowball effect of taking more things in and being able to step back a bit more and that's what the therapy has really done for me. It's really allowed me to look at things a lot more, the way I dress,*

the way I hold myself, the way I act around certain people, the way I interact with people I don't know. People with authority, people above me at work, people-- everybody, everybody and everything I now can sort of see-- I can take a second and look and think before acting. I now feel like everything I do I do with purpose. And I have the therapy to thank for that, that is sort of unlocked that ability for me. And I really do think it is just patience. That's what it's unlocked for me. (P14)

In this extract from P14, wider changes beyond improving sleep were described as a "snowball effect" – reflecting the sense of momentum and ever-growing impact. For this participant, despite the specific focus on improving sleep, the therapy helped change their perception of themselves and their abilities, giving confidence in their capacity to handle situations. This potential was within the participant but hard for them to access and the brief therapy helped them to "unlock" patience, perspective, and purpose.

The most commonly described benefits were better sleep, fewer voices and fears, and re-engagement with everyday life, for example:

Seeing things and hearing things has pretty much disappeared. I'm gonna be honest. ... Sleep and stress could always cause this stuff but it just started filtering away and of course the less it happens the less you realise that it happens, um, and its been so long since I've had any like noticeable episodes I guess um, that is just, its just kind of gone" (P6); "I think sleeping has improved my mood, I wake up happier and I think that sleeping better and being able to sleep faster in the, at night has lowered, you know, my voices at night (P15).

Sleep disruption was "fixed" (P15), and the benefits were tangible. Participants spoke of how anxiety and low mood improved, as well as a new-found level of confidence which allowed them to do things that previously felt out of reach, for example:

Yeah, it helped me boost my confidence so I could do more things like go to the shops, go to other places which I wouldn't normally go. Because normally I wouldn't sit on a bus or sit on a train on my own because I'd feel scared and I wouldn't do those things but over time I managed to do both things. (P9).

Improvements in energy levels and greater connection with others were often linked to improvements in daytime activity, as people began to re-engage in work, college, and the activities that matter to them. There were other wider improvements such as being able to think clearly, less

irritability, fewer suicidal thoughts, fewer appearance-related concerns, and better physical health. For the wider benefits participants described potential mechanistic routes to explain the pattern of change: noting that improved energy allowed re-engagement in activity, waking refreshed protected against low mood, thinking more clearly allowed more problem solving, and better sleep not only reduced stress in itself but helped give flexibility, patience, and confidence to cope in stressful moments. For some participants there were fewer changes, for others the changes were hard to sustain. Overall participants described greater ease, energy, and engagement in life.

Table 3.3. Additional illustrative quotes.

Theme 1: The challenge to access mental health treatment; "Bouncing between services"	
My experience with the other services was next to none. I went to my local out of hours and they just told me to take off days off and see how I feel. I told my GP I'm feeling pretty suicidal at the moment and they said, "can you hold on two weeks so we can get somebody in to talk about your mental health". I talked to them about it, said, "I don't know what's going on with me and I think I need some therapy for somebody to find out and possibly medication, something. I need something". I kept on saying that I really wanted something—anything. I had to book in an appointment, I couldn't get through to my GP. So, I genuinely felt then like OK, well I've been abandoned by them as well.	P14
I-- like cause I was doing a lot of like-- there was a lot of teams I was working with, with and that and unfortunately they couldn't help.	P16
Theme 2: Sleep problems and mental health difficulties are intertwined: "An obvious link"	
Well, obviously when you don't sleep very well at all, then you feel more drained and more tired and sad because you don't have the energy for things in your general life. Whereas, when you actually do get a good night's sleep, then you have that energy to be able to participate in everything you want to.	P11
I felt like I was trapped because I was in this constant state of low energy because of how horrible my sleep was. … I didn't feel like me at all. I felt like I just completely lost who I was. I felt genuinely empty. I thought I'd been like that before, but no, no this was a whole other animal.	P14
Sub theme: Bidirectional interaction between sleep problems and psychotic experiences	
For me, if I get a really bad night of sleep, I can end up being very angry in the morning, very down and if I get a good night of sleep, I'm very happy, very upbeat in the mornings and throughout the day I will be all good. In terms of when it comes to bad nights of sleep, I end up being very slow, very sluggish and very just down on that day. Yeah, during bad nights of sleep, if you haven't slept well at all, you can end up hearing things that are not there or seeing things that aren't really there. … I think it's just the matter of your brain hasn't had time to chill out, hasn't had time to reset itself that day and it's … since been continually working, it's overworked itself, if that makes sense?	P10
So, I think, cause when I'm going to sleep I'm someone who likes silence. Because the voices were that noise, just irritating or that's really what, and also the things they were saying would make me spiral and think but obviously first of all it was just having a noise in your head, it's like having someone with a microphone in your ear which is very hard to sleep with. And then also when I had the voices I then, this is going to sound very sad, but then get scared so then I want to turn the light on cause I'm in the dark and I don't want to be in the dark when I've got voices and I can't see anything. So, then I have the light on and obviously further disrupts the then going, the being able to go back to sleep.	P15

Theme 3: Flexibility in therapy delivery and provision matters: "Tailored to me as a person"	
Sub theme: Flexibility and rhetoric matter	
there was no miscommunication, which commonly happens when you're like… talking. But I think you guys were so good at making sure of what I was saying, like, you would double check what I was saying and then if you didn't understand you would ask me to explain again. And I think that's really good, 'cause some people just like… leave it.	P2
It was easy to understand better the different problems which made the cycle up and then how to break them by tackling each one of them. Because as soon as one was tackled out, the other three would stop.	P9
Sub theme: Active engagement and ownership: making the most of therapy	
I thought it was really, really helpful to see the actual progress that I was making because obviously it's more difficult to see it when you're just doing it. Whereas, if you just fill out a sheet that takes like a minute, and then look back at the one from last week, then you can actually see what's changed in that last week. Well, it showed me that it was working. So, that was really, really helpful. So, that made me want to persevere a bit more and see it out through to the end. That way I knew that I was actually going to get the best out.	P11
While I was doing the actual therapy, it was … I was sticking to it and it just kind of stuck. Now it's just quite normal now.	P7
Theme 4: Improving sleep leads to wider benefits: "Fixing the sleep helped everything else"	
I'm sleeping through the night and I'm being able to sleep when I get into bed. I think my mum's noticed that I'm not getting up throughout the night. I'm a lot less tired. Um… Just… making things a lot easier. I'm a lot less stressed.	P1
I think it definitely reduces stress because you're not waking up stressed, you're not waking up like, "I didn't sleep properly" and starting the day on bad terms, which makes it a lot easier to get on with the day while you've got energy and feel refreshed. So, it's definitely a stress-reliever and you start the day on good terms. And I think that already was better than how I was before when I would wake up and be like, "I don't feel good. The day is a bit rubbish." When I first started SleepWell, I was having those, like, hearing things and seeing things. That sort of faded. I'm not sure if that's to do with sleep or just in general. But that sort of went away. But the anxiety side and the low mood side has definitely been fixed due to the sleep improvement.	P8

3.6 Discussion

This peer methods qualitative study was an effort to try to understand the experience of sleep disruption and its treatment from the first-person perspective of young people at ultra-high-risk of psychosis. Participants were eager for help to improve sleep and mental health, despite a challenging journey to access support. Participants spoke of an obvious cycle of sleep problems and other mental health difficulties, including psychotic experiences, exacerbating each other. Treatment for sleep problems was highly valued. Consistent with the outcomes of the trial reported in Chapter 2, the participants described rapid and wide-ranging benefits that persisted over time. These results support the assertion that treating sleep problems may bring quick mental health

benefits. Whether intervening on sleep can have more preventative mental health benefits for young people at-risk of psychosis will be looked at within the new large multi-centre Sleeping Better trial (ISRCTN71800376).

3.6.1 The potential value of treating sleep problems

There was further consistency with the quantitative findings (Chaper 2; Waite et al., 2023): the treatment was popular, there were large changes in sleep, and participants described improvements in anxiety, depression, and psychotic experiences. The transformative benefits described by several of the participants in this study are consistent with the outcomes of a series of trials across the spectrum of severity of psychosis, all of which demonstrate large effect size improvements in sleep, very high uptake of therapy, and indications of the potential wider mental health benefits (Freeman, Waite, et al., 2015; Freeman et al., 2017; Sheaves, Freeman, et al., 2018).

The findings in this study are also consistent with other patient accounts of sleep disruption in the context of psychotic experiences, including: the wide impact of sleep problems (Chiu et al., 2016; Faulkner & Bee, 2017) and the value and benefits of treatments for sleep disturbance (Waite et al., 2018; Waite, Evans, et al., 2016). Both the sense of hopelessness at the outset of treatment and the eagerness for help is common in accounts from patients with persistent psychotic experiences (Chiu et al., 2016; Faulkner & Bee, 2017; Waite, Evans, et al., 2016) and those at elevated risk of psychosis (Waite et al., 2018), including an openness to the use of technology in treatment (Taylor et al., 2022), such as wearable devices (Griffiths et al., 2021).

3.6.2 The complexity of sleep presentations

Participants also described the complexity of sleep problems – the challenge of getting the right amount of high-quality sleep consistently at the right time. It is recognised that comorbidity of sleep problems is the norm, rather than the exception, in this clinical group (Dondé et al., 2022; Reeve, Sheaves, et al., 2019). Yet this raises challenges for precision both in the theoretical understanding and therapy delivery (Freeman & Waite, 2025; Harvey, 2022). Participants noted the successful application of specific treatment techniques – often after a collaborative period of experimentation and personalisation facilitated by the therapist. Notably regular in-session measurement was key to assessing the impact of potential techniques and boosting motivation. Greater precision in the measurement tools - accounting for the specific phenomenological

features of sleep problems in this group - may inform treatment development and enhance treatment outcomes.

3.6.3 The experience of therapy: personalisation is key

The findings in this peer methods study provide an insight into the dynamic process of therapy in which the specific style, content, and alliance enabled participants to take both an active role and degree of ownership of the resulting improvements. The importance of personalisation and tailoring was clear. This is consistent with other qualitative studies – for example in a study of young people at elevated risk of bipolar disorder participants spoke of the importance of therapy being "customised" to fit their individual needs (Jones et al., 2021). The flexible delivery of therapy – noted by the participants in this study - has also been highlighted in other qualitative accounts of psychological therapy with young people at risk of severe mental health problems (e.g. Gee et al., 2018). There was a notable contrast in this theme from some participants who self-identified as neurodivergent. There was a need for greater consistency and containment within the sessions. This is an area for potential development within this therapeutic approach – as well as more broadly in psychological therapies (see Stark & Authentistic Research Collective, 2021). The fundamental importance of the therapeutic alliance and sense of being able to share openly with a therapist is common across accounts with young people at ultra-high-risk of psychosis – indeed it was noted in the first qualitative study of a psychological intervention in the high risk field by a peer researcher (Byrne & Morrison, 2014). A particular advantage of sleep interventions in this ultra-high-risk group are that they are typically seen as non-stigmatising in comparison to other mental health interventions (Faulkner & Bee, 2016). This may be valuable in supporting uptake of treatment at a time when young patients often feel frightened and unsure of how to talk about their difficulties (e.g. Fusar-Poli et al., 2022). This may be particularly important in future implementation. There are promising initiatives to embed sleep interventions into youth mental health services (Rollinson et al., 2024), and potential opportunities within the NHS community transformation initiative. There may be a particular role for peers in the delivery of the intervention – as suggested in one of the accounts. Peer support workers draw on their lived experience of mental health problems to support others through similar difficulties. They are a growing workforce within the NHS (NHS England, 2019) – yet there have been no evaluations to date of peers delivering sleep interventions for young people at ultra-high-risk of psychosis.

3.6.4 The importance of peer-methods research

To the thesis author's knowledge, this is the first peer methods study to explore first person accounts of sleep disruption and its treatment in young patients at ultra-high-risk of psychosis. The peer researchers gave a particular opportunity to discuss experiences of therapy, as well as difficulties with sleep and other mental health problems, and bought this specific lens to the analysis. Whilst this gave a rich and nuanced perspective to the study (as is intended with peer methods - see Harding et al., 2010) this may have been enhanced by further encouraging dissensus with a recognition of the power of conflicting experiential knowledge (Speyer & Ustrup, 2025). It would also be valuable to seek further feedback from the peer-researchers regarding their experience of actively engaging as partners in the research process. In other peer-research with young people at ultra-high-risk of psychosis the role has been highly valued (Trimmel et al., 2024). Understanding the peer experience in terms of the flexibility, fluidity, and relational empowerment (Prebeg et al., 2023) could inform future peer-methods research.

3.6.5 Limitations

There are a number of limitations. Firstly, the research was conducted in a single centre in the UK and the participants will not be representative of all young patients attempting to access services. There was limited ethnic and gender diversity in the participants interviewed. Differential access to mental health services as well as treatment outcomes for psychosis are reported in young patients from minoritized backgrounds (Chui et al., 2021; Coelho et al., 2022; Morgan et al., 2017), especially Black African and Black Caribbean patients. Therefore, understanding the potential barriers faced by underrepresented groups will be important in both future evaluations of the therapy and implementation.

The sampling method was intended to maximise variation including with regards to therapy uptake, however as outlined above interviews were conducted only with people who had completed therapy, this was largely a reflection on the uptake of the therapy in the trial (only one person did not receive a treatment dose). There may be specific challenges for those participants who choose not to complete therapy, which will be more likely to be seen in larger trials. Similarly, there were extremely few people in the trial who did not improve their sleep from the intervention and their perspective will likely be different and was not captured in the current report. Therefore, one notable omission from the dataset is detailed insight into the potential challenges and

drawbacks of therapy. This is potentially due to sampling bias – as outlined above. It may also be due to difficulties in data collection. Peer methods were used to try to balance power and invite rich accounts. However, a clinical psychologist researcher was also present. For a subgroup of participants (n=6) this was the therapist they had worked with in the trial intervention. In recognition of this limitation in the data, a LEAP meeting was held specifically to consider the potential downsides and drawbacks of therapy. The LEAP identified the following areas for consideration: 1) investment of time and resources: *'Participants will have to take time out of their day to attend the therapy sessions'*, '*If therapy was delivered in-person there could be a travel cost associated with coming to therapy'* (note participants were offered reimbursement for travel to sessions in the trial); 2) the potential emotional demands of the intervention: *'sometimes people may have anxiety around booking therapy sessions due to anticipating the emotionality of the session', 'Talking about sleep could trigger memories, feelings, and emotions associated with bad sleep as well as focusing on the causes of bad sleep, so questions should be delicate and consider the effect their questions have on the participant'*; and 3) the content of the sessions: *'it might be difficult to talk about hearing voices in the therapy if it is a sensitive topic to the participant'*. These are all important insights regarding the potential adverse effects and demands of psychological interventions in this ultra-high-risk group. It will be valuable to investigate this further in future work.

Working within a peer methods framework a deliberate effort was made to seek out different perspectives, experiences, and expertise throughout the data collection and analysis. However, the persistence of an ableist bias is recognised in this work (common in qualitative research with patients with psychosis (Gupta et al., 2024)), reflected in the use of articulate illustrative quotes within the report. In line with recent recommendations (Gupta et al., 2024), it will be important to find routes to improve inclusivity with regards to neurodiversity and the range of ways people articulate and communicate.

It is also noted that the therapy was conducted during the COVID-19 pandemic. The context of restrictions and disruption, within services and day to day life, may have affected the experience of sleep disruption, mental health difficulties, and the therapy.

Young people at ultra-high-risk of psychosis face multiple mental health problems. Given sleep disruption is a putative contributory causal factor in the occurrence of mental health difficulties, treating sleep problems may be a valuable starting point for intervention – it provides focus amidst complexity, is quickly tractable, and may bring wider benefits to both the short and longer-term

trajectory. The next step is a definitive trial, with embedded mediation and moderation tests, to determine the wider effects. The Sleeping Better trial (ISRCTN71800376) is now underway.

Chapter Four

Conclusions

The programme of research presented in this thesis focused on developing and evaluating a psychological intervention targeting a developmentally important, potential contributory causal factor in the occurrence of psychosis - sleep disruption - in those at highest risk of psychosis. It was argued in this thesis that taking a targeted, mechanistic approach utilising interventionist-casual methods and working in collaboration with people with lived experience may provide a route to improve treatment outcomes for young people at ultra-high-risk of psychosis. The objectives of the research undertaken in this thesis were to 1) establish the feasibility and acceptability of a randomised controlled trial to treat sleep problems in young people at ultra-high-risk of psychosis; 2) provide proof of concept of the clinical efficacy of the treatment on sleep disturbance, affective symptoms, and psychotic experiences, and 3) gain a first-person perspective on the experience of the treatment. In this discussion chapter, a summary of the findings from the thesis will be presented, the limitations of the work beyond those covered in the previous chapters will be examined, and potential future directions for research on the topic will be set out.

4.1 Overview of findings

In Chapter 2, the first randomised controlled test of a psychological treatment for sleep problems in young people at ultra-high-risk of psychosis was described. In the trial, all feasibility markers were achieved (objective 1). Patients were successfully recruited (n=40; mean age 16.9 years, SD=2.5, range 14-23 years), there were very high follow-up rates (95%), and all assessments were completed by assessors blinded to group allocation. Treatment uptake (95%) and acceptability were both extremely high (median score 48, IQR 46 to 48; n=17; maximum possible score 48). The clinical outcomes indicate potentially large improvements in sleep at the end of treatment (Cohen's d =2.7, 95% CI -3.81 to -1.52), which were sustained at follow-up (d=1.9, 95% CI -3.06 to -0.77) (objective 2). There were also moderate reductions in depression, anxiety, and paranoia, and improvements in wellbeing, quality of life, and functioning. From this trial it is possible to conclude that it is feasible to research sleep treatment in patients at ultra-high-risk of psychosis and there may be a number of potential benefits on mental health symptoms. This provides the necessary foundations to inform the next phase of the research: a definitive test of the treatment.

The patient perspective of sleep disruption and its treatment in young people at-risk of psychosis was examined in Chapter 3, using a peer methods qualitative evaluation (objective 3). Peer research

is undertaken by people with relevant lived experience. Peer methods have the potential to level power, enhance rapport, and facilitate more nuanced and rich data collection and analysis (Harding et al., 2010; Terry & Cardwell, 2016). Semi-structured interviews were conducted with 16 participants (n=10 intervention, n=6 control) and data were analysed using reflexive thematic analysis. Four themes were generated: 1) The challenge to access mental health treatment ('Bouncing between services'); 2) Sleep problems and mental health difficulties are intertwined ('An obvious link'); 3) Flexibility in therapy provision matters ('Tailored to me as a person'); 4) Improving sleep leads to wider benefits ('Fixing the sleep helped everything else'). Participants were eager for help to improve sleep and other mental health problems. Participants described a frustrating journey to access treatment, marked by rejection and invalidation, which resulted in hopelessness and often resignation. The interaction between sleep disruption and other mental health difficulties was seen as obvious. Treatment for sleep problems was highly valued. The therapeutic style was characterised by a warm empathic stance and active, collaborative, sustained focus on improving sleep. Alongside flexible delivery methods, the therapeutic style and targeted treatment techniques enabled individuals to take an active role in therapy, enjoy ownership of their progress, and develop hope for the future. Consistent with the outcomes of the trial (Chapter 2), the participants described rapid and wide-ranging benefits – including better sleep, fewer voices and fears, and improved mood and confidence - that persisted over time. Improving sleep made a difference to everyday life. Routes to improve the treatment and trial experience for neurodiverse participants were highlighted. These results support the assertion that treating sleep problems may bring meaningful improvements in mental health.

Addressing sleep disruption is a meaningful clinical goal for young people at ultra-high-risk of psychosis. Successfully treating sleep problems may bring a wide range of health benefits, including reducing psychotic experiences. The causal-interventionist method employed in this thesis efficiently tested the potential clinical impact of the treatment and supported the premise of sleep disruption as a contributory causal factor in the occurrence of psychosis. This was the first time this targeted, single-focused, mechanistic approach had been used in the development of psychological treatments to prevent the emergence of severe mental health problems. The method could be applied to other putative psychological causal factors. The primary limitation of this work was that it was not designed or powered to detect clinical effects. A definitive trial, with embedded mediation and moderation, is needed to test the clinical effects indicated in this thesis. The multi-centre Sleeping Better trial (ISRCTN71800376) has subsequently started.

4.2 Clinical and theoretical implications

There are three important areas to highlight in regard to the clinical and theoretical implications. Firstly, the complexity and value of addressing sleep disturbance, secondly potential insights into the complex causal dynamics of mental health problems, and finally the importance of embedding lived experience within research practices.

4.2.1 The complexity and potential value of addressing sleep problems: supporting the paradigm shift

Sleep problems are common in young people at ultra-high-risk of psychosis (Bagautdinova et al., 2023; Clarke et al., 2021). They bring a range of negative effects including disrupted sleep timing, anxious waking in the night due to nightmares or unusual experiences, and difficulties in daytime functioning (Waite et al., 2018). Patients are keen for help (Waite et al., 2018). Yet few have received any treatment (Rehman et al., 2017; Stafford et al., 2024). The findings of the clinical trial outlined in Chapter 2 indicated that it may be feasible and acceptable to treat sleep problems in young people at ultra-high-risk of psychosis. Further to this the treatment may bring wider benefits, including improvements in mood, anxiety, and psychotic experiences. This was also clear in the first-person accounts detailed in the peer methods qualitative evaluation in Chapter 3. As such the findings of this thesis underscored the potential value of addressing sleep problems in young people at ultra-high-risk of psychosis. The potential treatment effects supported the hypothesis that sleep disruption is a contributory causal factor in the occurrence of psychotic experiences (Freeman, Sheaves, et al., 2020; Waite, Sheaves, et al., 2020) (rather than merely a secondary problem or epiphenomenon) and that this relationship may be mediated by negative affect (e.g. Bagrowska et al., 2022; Ballesio et al., 2022; Freeman et al., 2009; Kasanova et al., 2020). Yet there is still greater complexity and need for precision: sleep presentations varied widely.

It was clear in the baseline characteristics of participants and necessary therapeutic focus in the clinical trial (Chapter 2), as well as in the patient accounts (Chapter 3), that sleep problems were complex. Despite all participants scoring within the clinical range on a measure of insomnia to meet the trial inclusion criteria, there was wide variety in the clinical presentations. Circadian rhythm disruption, nightmares, and hypersomnia were all described by participants. This is consistent with accounts from young people at ultra-high-risk of psychosis (Waite et al., 2018) and the complexity and comorbidity of sleep presentations seen in early intervention in psychosis services in which 80% of participants had at least one sleep disorder and the mean number of sleep disorder diagnoses per patient was 3.3 (Reeve, Sheaves, et al., 2019). As such it is important to

attend to the phenomenology of sleep problems in this group - both within treatment (Freeman & Waite, 2025) and in causal explanations. Indeed, each sleep problem may have different causes and different contributions to specific psychotic experiences. This highlights the importance of understanding causal dynamics in the development of effective preventative treatments.

4.2.2 Insights in to complex causal dynamics

Investigating sleep disruption as a potential novel treatment target for psychotic symptoms provides a route to determine causality: if successful treatment of sleep problems results in improvements in psychotic experiences, then a causal relationship is demonstrated. Interventionist-causal methods provide a framework to conduct this test (Kendler & Campbell, 2009). They can be used to investigate both the treatment effect and the underlying theory regarding the putative causal factor – especially when tightened further by focusing on a single factor at a time (Freeman, 2011). The findings of this thesis supported this causal inference: that sleep disruption contributes to the persistence of psychotic experiences. Yet causality is complex: there are likely many inter-related contributory causal factors in the occurrence of psychotic experiences in those at high risk (Oliver et al., 2024). Further to this, insomnia and psychotic experiences share common causal influences – both genetic and environmental – meaning they can both arise from the same causes (Taylor et al., 2015). Mapping the clinical outcomes of the sleep intervention – as described in Chapters 2 and 3 – supports this multifactorial understanding of causation. Indeed the findings support the conceptualisation of mental health problems as occurring within a dynamic causal interplay as set out in network theory (Borsboom & Cramer, 2013). When conceptualised within these dynamic networks, highly connected problems become valuable treatment targets. Sleep disruption may be one such high value treatment target. It may be particularly pertinent to preventative work given the high rates of sleep problems in young people – the peak age of onset for mental health problems (McGrath et al., 2023; Solmi et al., 2022). And given the recognition in clinical staging models that broad spectrum treatments may be especially valuable in the less differentiated early phases of mental health problems (McGorry et al., 2014; Shah et al., 2020). Indeed some have argued for the broadening of preventative treatments beyond the ultra-high-risk criteria to youth mental health paradigms which account for the wide range of potential long term trajectories (Hartmann et al., 2019; McGorry et al., 2018).

The findings presented in this thesis demonstrated the potential value of interventionist-causal tests applied to a single factor in the development of psychological treatments for young people at

ultra-high-risk of psychosis. However, the understanding of causation as multifactorial means that there is no single cause nor that any treatment with a single causal focus will suffice. Therefore a range of potential treatments – each addressing specific causal factors – are required (van der Gaag et al., 2019). Precise assessment of implicated causal factors could facilitate a personalised menu of treatment options – each of which would likely bring effects throughout the network of inter-related problems. Such an approach requires testing.

4.2.3 The importance of embedding lived experience within research

Central to the work in this thesis has been the involvement of people with lived experience of sleep disruption and psychotic experiences. Peer methods, research that is conducted by people with relevant lived experience, has the potential to redistribute power within research (Harding et al., 2010; Terry & Cardwell, 2016). Consideration should be given to the flexibility, fluidity, and relational power in peer roles (Prebeg et al., 2023). Conducting research this way may also be highly valued by the peer researchers involved (e.g. Trimmel et al., 2024). Developing effective psychological treatments requires phenomenological precision (Freeman, 2024). Grounding innovation in first-person accounts and actively engaging those with lived experience in the development process has the potential to result in more nuanced, meaningful, and potentially effective treatments. The importance of embedding lived experience expertise and enhancing inclusion in research is reflected in the National Institute for Health and Care Research (NIHR) initiatives and funding requirements. The findings of this thesis owe much to the generosity and input of people with lived experience throughout every stage of the research process.

4.3 Limitations

There are of course broader limitations, outside the specific limitations for each study, to be acknowledged. The feasibility randomised controlled trial was an essential step in the translational pathway, yet it was not designed or powered to determine clinical effects. There was also wide variance in the clinical presentation of sleep disruption. Further limitations include the representativeness of the participants, the measurement tools employed, consideration of the developmental context, and preparation for implementation.

4.3.1 Complexity in the clinical presentation: the need for greater phenomenological understanding

One argument made in this thesis was that preventative psychological treatments may be refined by taking a specific focus on a single causal factor – in this thesis that was sleep disturbance. Yet the clinical presentations of sleep problems varied widely. There was disrupted sleep timing – phase advance (going to sleep early), phase delay (going to bed late), and irregular sleep schedules; difficulties getting to sleep and sustaining sleep; distressing experiences before sleep – such as night-time worry or hallucinatory experiences – and during sleep – such as nightmares or episodes of nocturnal panic. This variance in the presentations carries numerous implications. Firstly, this diversity suggests that sleep disruption is not a single, uniform phenomenon or causal factor but rather a range of issues. These distinct presentations may each carry different causal contributions and routes to psychotic experiences (e.g. Rek et al., 2017; Taylor et al., 2015). Statistical methods – such as structural equation modelling or network models - could now be used to analyse relationships between variables. Secondly, it is not known what proportion of participants had each type of sleep disturbance. Nor how this may have affected the outcomes of the trial. Thirdly, different types of sleep problems require different components of the treatment protocol (see Freeman & Waite, 2025). Therefore, the specific treatment delivered varied in response to the presentation of the individual patient. Individualisation is embedded in the treatment protocol and facilitated by the modular design of the treatment (i.e different booklets to be used based on the individualised formulation). However, to date this has been driven by clinical reflections rather than empirical data. It also raises challenges for potential future implementation.

4.3.2 Causality: the need for adequate power to test the clinical effects of the treatment

The trial presented in this thesis was a feasibility trial. It was not designed or powered to determine the clinical effects of the treatment, but rather to assess feasibility, acceptability, and to provide an initial proof of concept with regards to clinical outcomes. Therefore, there was insufficient power to test the treatment effects. To determine causality a sufficiently powered trial is required. This may also provide an opportunity to test wider outcomes, such as the binary outcome of transition to psychosis, and differences between subgroups such as the outcomes for neurodivergent participants (the necessity of which was highlighted in Chapter 3). Moreover, the study did not include an active comparison group to account for components of the treatment which might bring a clinical benefit, such as time with a clinician. As a result, while the design gives an indication of potential benefit over standard care, it does not determine which elements are necessary or if a different treatment could be more effective.

It should be noted that the argument set out in this thesis was that causation in the onset of serious mental health problems is likely complex, dynamic, and multifactorial. As such future mediation and moderation tests are needed to map the potential treatment effects across a range of (likely inter-related) outcomes and potential causal contributors. Mediation analyses will help determine which mechanisms drive change. Further work is also needed to test the specific components of the treatment and the order in which they are delivered to maximise benefit for the individual. This will of course vary by the particular sleep disorder presentation (Freeman & Waite, 2025). Therefore, greater precision in the phenomenology of the sleep and circadian rhythm disorders will facilitate treatment development.

4.3.3 Representativeness of the participants: the need to enhance inclusion

As was highlighted in Chapters 2 and 3, the generalisability of the findings is limited. The research was conducted in a single centre in the UK and the participants will not have been representative of all young patients attempting to access services. There was limited ethnic and gender diversity in the participant cohort. Differential access to mental health services as well as treatment outcomes for psychosis are reported in young patients from minoritised backgrounds (Chui et al., 2021; Coelho et al., 2022; Morgan et al., 2017), especially Black African and Black Caribbean patients. The need for greater diversity and inclusion in clinical trials has been highlighted by initiatives such as the Research Inclusion Strategy set out by the National Institute for Health and Care Research (NIHR, 2022). This is particularly pertinent for psychosis research (Burkhard et al., 2021). For example, people from minority backgrounds may have greater exposure to specific risk factors related to social adversity and discrimination. A key part of successful prevention is identifying the people who could benefit from an indicated intervention, therefore understanding the potential barriers faced by underrepresented groups and addressing issues of access and inclusion will be essential in future work.

Within the peer methods qualitative evaluation (Chapter 3), different perspectives, experiences, and expertise were purposively sought throughout the data collection and analysis. However, an ableist bias, for example the use of articulate illustrative quotes, remains - which is common in qualitative research with patients with psychosis (Gupta et al., 2024). In future qualitative work it will be necessary to find methods to improve inclusivity with regards to neurodiversity and the range of ways people articulate and communicate. Further to this, the sampling method was intended to maximise variation of therapy uptake and experience. However, only those who

completed therapy were interviewed. This reflected the uptake of therapy in the trial, in which all but one participant received the prespecified treatment dose. Yet, there may be specific challenges for those participants who choose not to complete therapy. Similarly, there were extremely few people in the trial who did not improve their sleep. As such the specific challenges faced by individuals who do not complete therapy and the perspectives of those who did not experience sleep improvement were not captured. These important viewpoints are likely to become more apparent in larger trials.

The rate of transition to psychosis within the clinical trial (Chapter 2) was low. This may be a reflection of the nine-month timeframe for follow up – with estimates for transition typically measured at 12 or 24 month (Fusar-Poli et al., 2020). It is also possible that the methods for recruitment did not identify those at highest risk. Although outreach to primary care practitioners may increase access (e.g. Radez et al., 2023), the focus of recruitment for the clinical trial was intended to reflect current service provision and therefore recruitment was via secondary mental health services (with two thirds identified via specialist early psychosis services and one third from child and adolescent mental health services). Consistent with this secondary care focus, the severity scores on the CAARMS were higher than those in other trials of psychological interventions for young people at risk of psychosis (e.g. Morrison et al., 2012). However, future work will need to ensure those at highest risk are correctly identified and included. This is a key area of development within the field of prevention as there is recognition that greater precision in early detection is needed (Oliver et al., 2022) and tools to enhance the accuracy of identification are in development, for example algorithm driven assessment measures (Paino et al., 2022).

4.4.4 Measurement: the need for greater precision

Effective identification and evaluation of sleep issues depend on precise measurement. The primary clinical outcome used in this thesis was a self-report measure of insomnia. Yet the sleep presentations in young people at ultra-high-risk are complex and it is likely this measure missed some of the key features of sleep disruption in this clinical group such as oversleeping and disrupted sleep timing. A more accurate tool would be helpful to capture fully the complexity and range of sleep problems in the target group and track meaningful outcomes of treatment such as reducing oversleeping or aligning sleep timing with the ideal circadian pattern. The measure also needs to account for the developmental context – this is particularly pertinent given the biological changes in sleep timing during adolescence and the specific social context that adolescents and emerging adults face, such as undertaking exams and living independently for the first time. Few

measures of sleep disturbance have been validated for use in adolescents and emerging adults (Illingworth et al., 2024). And even fewer have been developed specifically for this age group. To increase accuracy in the assessment of treatment outcomes it would be beneficial to develop a new measure that is: phenomenologically complete, capturing the range and complexity of sleep problems in this group; sensitive to the developmental context; and mechanistically informed. Collaborating with individuals who have direct lived experience would be essential to developing a measure that accurately identifies and articulates the clinical problem. It will be useful in future treatment development and evaluation to also track the factors underpinning sleep – such as circadian rhythm, homeostatic load, and level of arousal to understand how the treatment works. Further to this, no objective measures of sleep or sleep architecture were included in the work presented in this thesis. Understanding how treatment techniques interact with sleep architecture may prove a useful route to refine further the treatment.

4.4.5 Developmental context: the need for understanding and adaptation

Greater attention to the developmental context would be helpful. The age range of participants included in this thesis (14-25 years old) was focused on the peak age of onset of psychosis and definition of clinical high risk for psychosis (Solmi et al., 2022; Yung & Nelson, 2013; McGrath et al., 2023). Yet this age range spans significant developmental milestones, meaning the needs of a 14-year-old may differ substantially from those of a 24-year-old participant. As such, the treatment was personalised to fit the individual – for example, the therapist also working with parents and schoolteachers if an adolescent was living at home and undertaking mandatory education (until age 16 years in UK) or engaging with a partner or employer for a young adult. Further to this the therapy materials were informed by work with adult patients with established psychosis (e.g. Waite et al., 2016). Whilst a review of materials was conducted with young expert by experience advisors and adaptations to language and content were made, such as highlighting the delayed phase circadian shift and use of devices at night-time, more could have been done to address the developmental stage of participants. The small number of participants in the current trial prevented a detailed analysis of how developmental differences impacted the treatment, or what further adaptions may be needed. Notably there was no investigation of the impact of the intervention on the wider social system. The views of family members and carers will be important to include in future work.

4.4.6 Implementation: the need for preparation and delivery at scale

The delivery of the intervention in the feasibility trial (Chapter 2) was by specialist clinical psychologists. This method of delivery will not be implementable at scale. Nor will the therapists have been representative of all clinicians delivering therapeutic interventions in mental health services. Further work will be required to ensure the treatment is accessible. This may include delivery by non-specialists. Preliminary evaluations of implementation of sleep interventions by non-specialists within youth mental health services indicate this may be a feasible route for delivery (Rollinson et al., 2024). However, the training, sustainability, and clinical outcomes need testing in young people at ultra-high-risk of psychosis. Detailing the values and therapeutic style of the treatment may also be of value. It is also recognised that broader and earlier preventative approaches may be useful – such as population level preventative interventions delivered in schools (e.g. Radez et al., 2024). Given sleep interventions are typically perceived as non-stigmatising in comparison to other mental health interventions (Faulkner & Bee, 2017), successful implementation of these approaches may be particularly important for young people at high-risk of psychosis.

4.4 Future directions

The findings presented in this thesis potentially provide an empirical and clinical foundation to advance the development of preventative treatments for young people at ultra-high-risk of psychosis. Several areas now merit examination. Firstly, the evaluation of the intervention in a definitive trial. Further to this there are routes to refine the treatment and consider greater mechanistic understanding. Secondly, there is the application of the interventionist-causal framework, employed in this thesis, to other putative psychological mechanisms implicated in the occurrence of psychotic experiences.

4.4.1 Evaluating and refining the SleepWell intervention: a definitive trial

The primary limitation of the work described in this thesis is that the feasibility randomised controlled trial was insufficiently powered to provide a definitive test of the targeted psychological treatment for sleep problems in young people at ultra-high-risk of psychosis. Therefore, firstly, a definitive trial to test the treatment effects is required. The definitive trial provides an opportunity to test the effects on the primary outcome, sleep disruption, and on the other key secondary outcomes: anxiety, depression, and psychotic experiences. A larger trial also provides an opportunity to test the effects on transition to psychosis as a binary outcome. However, the

theoretical and clinical argument set out in this thesis is that reduction in the psychotic experiences, rather than the binary transition, should be prioritised given transition is only one point on the continuum of psychotic experiences and there are a range of potential diagnostic outcomes including bipolar disorder, major depression and personality disorder as well as poor long-term trajectories in those who do not transition to psychosis (or other severe mental health problems) (Addington et al., 2019; Carrión et al., 2013; Lin et al., 2015). Further to this, longer term follow-up – outside the scope of a typical trial period – is required to determine transition rates. With improvements in the collection and availability of routine clinical data (i.e. medical notes, Mental Health Service Data Set) longer term follow-up by tracking transitions in medical records may become possible, the feasibility of such approaches is under investigation (e.g. Hamilton et al., 2023).

A definitive trial also provides an opportunity to test the effects of the treatment on important outcomes that were not included in the current feasibility trial, such as the effects on negative symptoms. Negative symptoms have typically been overlooked, both in patients with a diagnosis of psychosis and in young people at ultra-high-risk of psychosis. Currently there is little evidence of any effective treatments for negative symptoms in those at ultra-high-risk of psychosis (Devoe et al., 2018, 2019). Yet treating sleep problems may bring benefits. It is theoretically plausible that poor sleep contributes to low energy, low motivation, and low mood. Indeed, treating sleep problems may be a route to achieve patient defined outcomes of recovery – which centre on re-establishing agency, restoring relationships, enhancing hope and purpose, and being able to sufficiently cope with difficulties to re-engage with everyday life (Jordan et al., 2024). Sleeping Better a large multi-centre definitive trial funded by the Wellcome Trust (ISRCTN71800376) and designed to assess primary, key secondary, and broader clinical outcomes, including negative symptoms and recovery, is now underway.

Secondly, the mechanistic picture is still far from complete. This is at both the level of how sleep disruption contributes to the occurrence and persistence of psychotic experiences, and how the treatment works with regards to the key targets of the therapy (sleep pressure, circadian rhythm, and level of arousal). With regards to how sleep disruption might contribute to the occurrence of psychotic experiences, a number of potential mediators have been identified including emotion regulation (Grezellschak et al., 2017; Rehman et al., 2018), dissociation (Koffel & Watson, 2009; Van Der Kloet et al., 2013), and negative affect (e.g. Bagrowska et al., 2022; Ballesio et al., 2022; Freeman et al., 2009; Kasanova et al., 2020; Reeve et al., 2018). To date, negative affect has been particularly prominent in explanatory accounts, especially with regards to paranoia. Future work

evaluating the mechanistic route through which sleep disturbance contributes to psychotic experiences may inform conceptualisations of the multi-causation of mental health problems. This work will need to account for the wide range of sleep presentations in this clinical group. At another mechanistic level, the treatment was designed to focus on the three factors that affect sleep: 1) homeostatic load, 2) circadian rhythm, 3) level of arousal (Borbély, 1982; Riemann et al., 2022; Saper et al., 2005). Understanding how the treatment affects each of these mechanisms and the impact of this on the outcome of treatment will provide another route to refine the treatment further.

Thirdly, a more detailed understanding of treatment moderators is required. In particular, to identify who gains benefit and most importantly who does not. This will reveal potential routes to refine the treatment. Within the feasibility trial, there was a group of five participants who showed limited (n=3), delayed (n=1), or no (n=1) benefit on the Insomnia Severity Index (Bastien et al., 2001). Further to this the peer methods evaluation (Chapter 3) noted the importance of suitably adapting the treatment for neurodivergent participants. Although this gives initial clues for potential further treatment refinement, only in a larger definitive trial will moderation effects be suitably tested. Yet even then it is possible, perhaps even likely, moderation will concern unmeasured factors. Another method to understand differences in treatment outcome is the evaluation of the trajectories of change using in-session data. This approach has recently been applied within trials of psychological therapies for psychosis (e.g. Jenner et al., 2024), and trials of pharmacological treatments in people at ultra-high-risk of psychosis (e.g. Hartmann et al., 2020). Collecting in-session data and applying statistical methods, such as latent class trajectory analysis, provides a route to consider differential treatment effects and patterns of benefit, such as those who show an early gain. However, this is further complicated in the sleep intervention due to the different types of sleep difficulties young patients experience. As such it may be necessary to account for the specific phenomenology of the sleep problem – such as insomnia, circadian rhythm disruption, nightmares, hypersomnia - prior to assessing the trajectories of change.

Fourthly, further to the clinical effects, cost-effectiveness must also be evaluated. Existing psychological interventions (Cognitive Behavioural Therapy typically delivered over 16 sessions) in this high-risk group have shown to be not only cost effective (Ising et al., 2015) but also cost-saving (Ologundudu et al., 2021). Given the comparative brevity of this sleep intervention (eight sessions) it may also be cost-effective. Yet health economic analysis is required both for the evaluation of health service costs and wider societal costs, particularly given the high levels of young people not in education, employment, or training in this clinical group and who typically

have very poor long term functional outcomes (Public Health England & UCL Institute of Health Equity, 2014).

Finally, a focus on potential implementation models and effectiveness evaluations will be required if the treatment shows clinical benefit. It is imperative that any intervention in this high-risk group is accessible. Therefore, consideration must be given to the delivery model and service context. The service context also varies by country and health service model. Therefore, it is likely a number of implementation models, each of which accounts for the local health service context, may be required. Potential delivery models include expanding the range of health professionals who can deliver the treatment, for example taking advantage of the wider range of psychological professionals such as graduate mental health workers and considering how the treatment may particularly benefit from delivery by people with similar lived experiences, such as peer support workers, as flagged in the qualitative accounts in Chapter 3. Peer support workers draw on their lived experience of mental health problems to support others through similar difficulties. They are a growing workforce within the NHS (NHS England, 2019). Given the peer methods approach described in Chapter 3 and suggested directly by participants, the model of drawing on lived experience may be suited to discussions of and treatments for sleep problems. Initial evidence indicates the feasibility of non-specialists delivering sleep interventions within youth mental health services (Rollinson et al., 2024). Delivery via peer support workers is yet to be tested. It is also possible that delivery in other service settings may be valuable – for example, there are high rates of sleep disturbance in adolescent inpatient wards (Johnsen et al., 2024). Greater precision in the measurement and description of sleep problems in this group (e.g. Freeman & Waite, 2025) will likely be required to successfully support delivery by non-specialists. It will also be important to provide adequate descriptions of the specific style of the therapy - which was highlighted in the qualitative accounts. Another route for implementation may be through digitisation. Digital approaches for sleep interventions exist and have been effective in increasing service provision for Cognitive Behavioural Therapy for insomnia (Drake, 2016; Espie & Henry, 2023; Sweetman et al., 2021). However, the standard programmes do not currently incorporate the treatment adaptations nor therapy style detailed in the current SleepWell intervention examined in this thesis. Therefore, further participatory design work in collaboration with people with lived experience of the problem would be required to co-produce, and evaluate, a digital version of the treatment.

4.4.2 A potential approach for testing putative causal factors

The research presented in this thesis is underpinned by earlier positive outcomes of cognitive behavioural approaches in the high risk group (e.g. Morrison et al., 2012; van der Gaag et al., 2012). To further refine cognitive behavioural treatment approaches in this ultra-high-risk group a targeted, mechanistic focus on a single psychological causal factor was evaluated using interventionist-causal methods. The theoretical stance taken was one of multifactorial causation – assuming that there are multiple contributory causal factors that interact in a dynamic interplay and that these may vary, at least to some degree, between individuals (e.g. Freeman & Loe, 2023). Therefore, treatment can target common specific and non-specific factors (such as sleep disturbance – which have typically been overlooked to date (Waite, Sheaves, et al., 2020)). Targeting these factors in individuals at highest risk of psychosis brings the potential to derive benefit in the specific treatment target and potential wider effects throughout the network. This strategy could bring dual benefits. It has the potential to bring both direct and indirect effects – through multiple routes – to reduce psychotic experiences and overall psychosis risk. Tackling the common, causal factors young people at high risk of psychosis are often help-seeking for – such as low mood and anxiety (Falkenberg et al., 2015) - may also increase treatment uptake.

Employing a casual-interventionist paradigm – with a specific single focus of the intervention to bring greater confidence in the conclusions drawn from the work – facilitates the testing of the treatment and the underlying theory simultaneously, potentially expediting clinical translation (Freeman, 2011). This approach has been successfully applied in the systematic development of a targeted, mechanistic treatment for persecutory delusions (Freeman, 2016; Freeman, Emsley, et al., 2021). A series of randomised controlled trials were conducted - each focused on a particular causal candidate (e.g. Freeman, Dunn, et al., 2015; Freeman, Waite, et al., 2015) A specific therapeutic style was developed (Freeman & Waite, 2017). The interventions were then combined in to a comprehensive treatment programme (Freeman, Emsley, et al., 2021). This approach to treatment development could now be applied in young people at ultra-high-risk. (Alternatively, mediation tests could be used to derive the specific treatment benefits of a comprehensive multi-component treatment.) To achieve this a potential future direction of this work is the application of this single focused causal-interventionist approach to other putative psychological mechanisms implicated in the occurrence of psychotic experiences in those at highest risk of psychosis. One such mechanistic target is processing traumatic experiences (van der Gaag et al., 2019). Three further examples - each of which is developmentally important, problematic in its own right, that young patients want help for, and is potentially a causal contributor - are outlined below.

Self-concept (how we think and feel about ourselves) shapes our interaction with the world. Identity formation has been recognised as a key developmental task throughout adolescence and early adulthood [since being conceptualised as a challenge between identity and confusion (or confidence vs inferiority) by Erikson in the 1950s]. Negative self-concept is common in patients with psychosis (Freeman et al., 2019) and in young people at ultra-high-risk of psychosis (Bemrose et al., 2021; Cowan et al., 2019; Crowter et al., 2022; Taylor et al., 2014). It predicts the occurrence and persistence of paranoid thinking (Bird et al., 2017) and depression and anxiety in those at high risk (Cowan et al., 2019). Specific components of self-concept such as body image – which is associated with psychotic experiences (Waite, Diamond, et al., 2023; Waite et al., 2019) - may be particularly relevant in adolescents (Waite & Freeman, 2017). In experimental tests reducing negative self-beliefs and improving positive self-beliefs both provide routes to reduce psychotic experiences (Brown et al., 2020) with changes in self-belief mediating changes in paranoia. Treatments show promise in patients with psychosis (Freeman et al., 2014, 2023), however these approaches are yet to be tested in young people at high risk.

Perseverative thinking, often termed worry (when future focused) or rumination (when past focused) is the difficulty disengaging from negative thoughts. It is a cognitive process which brings negative ideas to mind and keeps them there. It is implicated in the occurrence of a wide range of mental health problems (Ehring & Watkins, 2008), including psychotic experiences: it predicts the occurrence and persistence of paranoid thinking (Bird et al., 2017; Freeman et al., 2012) and is common in patients with psychosis (Freeman et al., 2019). A brief, targeted, psychological intervention has been shown to reduce both worry and paranoia in patients with persistent psychosis (Freeman, Dunn, et al., 2015). Mediation analyses indicate a causal contribution of worry to paranoia: two thirds of the effect on delusions was mediated by changes in worry. However, potential preventative effects in those at highest risk has not yet been tested.

Emotion dysregulation (the difficulty of tolerating and modifying emotional reactions) is common across mental health problems including the spectrum of severity of psychosis (Chapman et al., 2020; Ludwig et al., 2019). It is implicated in the persistence of psychotic experiences. For example, affective reactivity, the degree to which an event is perceived to be overloading, uncontrollable, or unpredictable, predicts the occurrence and persistence of paranoid thinking in adolescents (Bird et al., 2017), and emotional avoidance, difficulty experiencing or acknowledging emotions, predicts the persistence of voice hearing (Varese et al., 2016). Developing strategies to regulate emotions is a key developmental task in adolescence and emerging adulthood (Ahmed et al., 2015; Silvers, 2022). Therapeutic approaches to support this process show benefits across a wide range of mental

health outcomes (Berking et al., 2008; Saccaro et al., 2024), yet the effects on psychotic experiences are to be determined. This provides another potential treatment target for young people at risk of psychosis.

Taking this work even further forward, it is conceivable that a menu of treatment options, each addressing a putative causal factor and specific psychotic experiences, could allow for personalisation and patient choice. This is important given the heterogeneity in the clinical high risk group (Fusar-Poli et al., 2016). Consistent with clinical staging models (e.g. McGorry et al., 2014; Shah et al., 2020), the treatment components could also be combined into a longer treatment – as it is unlikely addressing a single causal factor will be sufficient to bring the required treatment effects on reducing the onset of severe mental health problems.

The programme of research in this thesis highlights that sleep problems are an important clinical target for young people. Psychological intervention may bring wider benefits and possibly help prevent the emergence of severe mental health problems. Definitive testing, with embedded mediation and moderation, is now required. Working with people with relevant lived experience, as advisors and as peer researchers, brings greater depth and insight to the work, enhancing the applicability, acceptability, and outcomes. Targeting individual putative mechanisms using a causal-interventionist framework, confined to a single treatment focus, allows simultaneous testing of clinical treatments and the hypothesised theoretical conceptualisation, potentially accelerating the translational pathway. Other psychological contributory causal factors could also be investigated as conceivable treatment targets. This is one potential route for treatment development. As such this translational, causal-interventionist approach, conducted in collaboration with people with lived experience, may provide a methodological framework to develop and test treatments. Investing in this approach may provide a novel route to improve treatment outcomes for young people at ultra-high-risk of psychosis.

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Appendices

Chapter 1

1.1 Published manuscript: Waite, F., Černis, E., Kabir, T., Iredale, E., Johns, L., Maughan, D., Diamond, R., Seddon, R., Williams, N., Yu, L.-M., & Freeman, D. (2023). A targeted psychological treatment for sleep problems in young people at ultra-high risk of psychosis in England (SleepWell): A parallel group, single-blind, randomised controlled feasibility trial. *The Lancet Psychiatry*, *10*(9), 706–718. https://doi.org/10.1016/S2215-0366(23)00203-1

1.2 Published manuscript: Waite, F., Sheaves, B., Isham, L., Reeve, S., & Freeman, D. (2020). Sleep and schizophrenia: From epiphenomenon to treatable causal target. *Schizophrenia Research*, *221*, 44–56. https://doi.org/10.1016/j.schres.2019.11.014

Chapter 2

2.1 Published manuscript: Waite, F., Černis, E., Kabir, T., Iredale, E., Johns, L., Maughan, D., Diamond, R., Seddon, R., Williams, N., Yu, L.-M., & Freeman, D. (2023). A targeted psychological treatment for sleep problems in young people at ultra-high risk of psychosis in England (SleepWell): A parallel group, single-blind, randomised controlled feasibility trial. *The Lancet Psychiatry*, *10*(9), 706–718. https://doi.org/10.1016/S2215-0366(23)00203-1

2.2 Ethics approval: Health Research Authority

2.3 Ethics approval: Confirmation of local Capacity and Capability – Oxford Health NHS Foundation Trust

2.4 Ethics approval: Confirmation of local Capacity and Capability – Berkshire Healthcare NHS Foundation Trust

2.5 CONSORT checklist

2.6 Therapy adherence tool

2.7 Outcome measure: Insomnia Severity Index

2.8 Outcome measure: Comprehensive Assessment of At Risk Mental States

2.9 Outcome measure: Revised Green et al Paranoid Thoughts Scale

2.10 Outcome measure: Depression, Anxiety, and Stress Scale

2.11 Referrals by service type

2.12 Data completion rates of measures

Chapter 3

3.1 Published manuscript: Waite, F., Evans, S., Rebello, A., Sharpe, T., Otaiku, J., Iredale, E., Kabir, T., Černis, E., & Freeman, D. (2025). Sleep disruption and its psychological treatment in young people at risk of psychosis: A peer methods qualitative evaluation. *British Journal of Clinical Psychology*, 65, 746–761. https://doi.org/10.1111/bjc.70002

3.2 Invitation and outline of the interview co-facilitator role

3.3 Template peer researcher 'Working Well Together Plan'

3.4 Interview schedule: Participant copy of interview questions

3.5 Analysis: Extract of preliminary coding

3.6 Analysis: Example coding structure for individual participant

3.7 Analysis: Example thematic map and coding structure across participants

Chapter 1

1.1 Published manuscript: Waite, F., Černis, E., Kabir, T., Iredale, E., Johns, L., Maughan, D., Diamond, R., Seddon, R., Williams, N., Yu, L.-M., & Freeman, D. (2023). A targeted psychological treatment for sleep problems in young people at ultra-high risk of psychosis in England (SleepWell): A parallel group, single-blind, randomised controlled feasibility trial. *The Lancet Psychiatry*, *10*(9), 706–718. https://doi.org/10.1016/S2215-0366(23)00203-1

BMJ Open

Treating sleep problems in young people at ultra-high-risk of psychosis: study protocol for a single-blind parallel group randomised controlled feasibility trial (SleepWell)

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ABSTRACT

Background Effective interventions, targeting key contributory causal factors, are needed to prevent the emergence of severe mental health problems in young people. Insomnia is a common clinical issue that is problematic in its own right but that also leads to the development and persistence of psychotic experiences. The implication is that treating sleep problems may prevent the onset of psychosis. We collected initial case series data with 12 young people at ultra-high-risk of psychosis. Post-intervention, there were improvements in sleep, depression and psychotic experiences. Now we test the feasibility of a randomised controlled trial, with a clinical aim to treat sleep problems and hence reduce depression, psychotic experiences, and prevent transition to psychosis.

Methods and analysis A randomised controlled feasibility trial will be conducted. Forty patients aged 14 to 25 years who are at ultra-high-risk of psychosis and have sleep disturbance will be recruited from National Health Service (NHS) mental health services. Participants will be randomised to receive either a novel, targeted, youth-focussed sleep intervention in addition to usual care or usual care alone. Assessor-blinded assessments will be conducted at baseline, 3 months (post-intervention) and 9 months (follow-up). The eight-session psychological intervention will target the key mechanisms which disrupt sleep: circadian rhythm irregularities, low sleep pressure, and hyperarousal. To gain an in-depth understanding of participants' views on the acceptability of the intervention and study procedures, 16 participants (n=10 intervention, n=6 control) will take part in qualitative interviews. Analyses will focus on feasibility outcomes (recruitment, retention, and treatment uptake rates) and provide initial CI estimates of intervention effects. Thematic analysis of the qualitative interviews will assess the acceptability of the intervention and trial procedures.

Ethics and dissemination The trial has received ethical approval from the NHS Health Research Authority. Findings will be disseminated through peer-reviewed publications, conference presentations, and lay networks.

Trial registration number ISRCTN85601537.

Strengths and limitations of this study

- *Importance of the study:* The SleepWell trial is the first randomised controlled test of a sleep intervention in young patients at ultra-high-risk of psychosis.
- *Causal-interventionist paradigm:* This is the first randomised controlled trial to target a single causal factor in the ultra-high-risk group: the randomised controlled design has the aim of lessening sleep disturbance in the intervention group, thereby testing the underlying theory that sleep disruption is a contributory causal factor in the occurrence of psychotic experiences (most likely via reductions in negative affect).
- *Data collection methods:* The study uses mixed methods (interviews, questionnaires and wearable technology) to address the research questions.
- *Follow-up period:* The follow-up period is 9 months; however, the risk of onset of psychosis may be elevated for longer, meaning that we cannot capture all information about transition rates.
- *Control condition:* There is no active control, so it is not possible to determine which elements of the intervention may produce change.

BACKGROUND

Rationale

The peak age of onset for mental health problems, including psychosis, is between the ages of 14 and 25 years. Three quarters of all lifetime instances of mental health disorders have started by the age of 24.[1] There is increasing recognition of the need to develop preventative approaches.[2] We focus on psychosis, with an emphasis on developing interventions that result in both immediate and longer-term improvements by individually targeting developmentally important, transdiagnostic causal factors, that are problematic in their own

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right and that young patients want treated. Sleep disturbance is one such issue.

In young people, sleep disruption is associated with poor physical and mental health and worse social outcomes, including greater suicide risk, obesity, and lower educational attainment.[3 4] Yet, sleep problems have been historically understood as either a symptom of psychiatric disorder or a non-specific epiphenomenon (ie, a secondary problem). Recent research has turned this traditional view on its head and instead shown that sleep disruption is one causal factor in the occurrence of psychotic experiences.[5 6]

When sleep is deliberately reduced, in experimental manipulation studies, it results in an increase in psychotic experiences.[7] Increases in psychotic experiences due to worsening of sleep are mediated by increases in negative affect and related processes (such as worry and negative self-views).[7] Conversely, successfully treating sleep problems leads to an improvement in psychotic experiences. A large randomised controlled trial (RCT) with 3755 university students found that psychological treatment was highly effective for treating insomnia and led to significant improvements in non-clinical hallucinations and paranoia.[8] Sleep treatment in this trial also reduced the likelihood that students would reach the threshold for being at ultra-high-risk of psychosis.

In young people at ultra-high-risk of psychosis, sleep problems are widespread, with estimates of prevalence exceeding 75%.[9] Insomnia and circadian rhythm disruption are associated with the severity of psychotic experiences and poor outcomes.[10–13] Findings from a large European prospective multicentre study indicate that sleep problems are highly predictive of transition to psychosis.[14] In addition, sleep disturbance is also a contributory factor across a wide range of other mental health problems, including anxiety, depression, and bipolar disorder.[6 15] Therefore, treating sleep problems may also prevent other mental health problems, such as depression and anxiety, and promote improvements in functioning and physical health.

The key diagnostic marker for identifying young people at ultra-high-risk of psychosis is the presence of attenuated (subthreshold frequency or intensity) psychotic experiences (APE). Yet APE are a marker of potential risk for a number of different serious mental health problems, including personality and mood disorders.[16] Even for young people who experience APE but do not go on to meet diagnostic criteria for psychosis (or other serious mental health problems) the long-term outcomes can remain poor.[17 18] The clinical staging model in psychiatry emphasises that less differentiated early phases of mental health problems may benefit from broad spectrum and simpler treatments.[19–21] From a network perspective, mental health problems arise from the causal interplay (both direct and reciprocal) between different symptoms.[22] Therefore, targeting one specific symptom, such as sleep disturbance, will have an impact on other causally connected problems, such as low mood, anxiety, and psychotic experiences.

Cognitive Behavioural Therapy for insomnia (CBTi) is the first-line treatment for adults with insomnia[23 24] and has been effectively adapted for people with psychosis.[5 25 26] Not only does CBTi lead to large improvements in insomnia, but there are also significant effects on depression and anxiety,[8 25 27] and smaller effects on psychotic experiences.[8 25] It is likely the treatment effects on psychotic experiences are mediated by improvements in depression and anxiety.[8 27] In light of this previous work, we now want to test the effects of treating sleep problems to reduce psychotic experiences and prevent the onset of psychosis in those at highest risk. We are also interested in whether this treatment focus reduces emotional disorders both in the short and long-term.

Building on the principles of CBTi and our work treating insomnia in adults with psychosis, we developed a brief psychological intervention to address sleep problems in young people at ultra-high-risk of psychosis (SleepWell).[28] The core treatment techniques include stimulus control, circadian realignment, and regulating daytime activity. In an uncontrolled case series with 12 young people at ultra-high-risk of psychosis, outcome assessments were conducted pre-treatment, post-treatment, and at a 1-month follow-up. Following the intervention, there were improvements in sleep (d=6.8), depression (d=0.5), and psychotic experiences (paranoia d=0.6 and hallucinations d=0.3) and the changes were maintained at the 1-month follow-up. Throughout the 10-week study period, no participants transitioned to psychosis. In the opposite direction, at the end of the study three participants no longer met criteria for being at ultra-high-risk of psychosis. The treatment was popular (for example, 89% attendance rate) and patients were keen to participate. In qualitative interviews, participants described achieving meaningful change in both sleep and well-being by developing a 'repertoire of skills'.[29] The treatment now requires testing in a randomised trial to determine the effects on psychotic experiences and the potential to prevent the onset of psychosis.

Due to limitations in statistical power, we will investigate the effects of the sleep treatment on the dimension of psychotic experiences rather than relying solely on the dichotomous outcome of transition. In line with the findings from all previous studies, we expect that the effect of improving sleep on psychotic experiences will be through improvements in negative affect (depression and anxiety), which is a mediator we are also interested in as an outcome in itself.

Objectives

We aim to assess the feasibility of a targeted intervention to improve sleep and prevent psychosis in young people at ultra-high-risk of psychosis.

The primary objective is to assess the feasibility and acceptability of a targeted sleep intervention to prevent psychosis in young people at ultra-high-risk in order to

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Table 1 Summary of objectives and assessment measures

	Objectives	Outcome measures
Primary	Assess the feasibility and acceptability of a targeted sleep intervention to prevent psychosis and to establish key parameters for a future randomised controlled trial.	Number of patients identified, recruited, declined and retained. Number of referrals made per site, and per service type, per month. Service use as measured on the CSRI. Completion rate of each assessment measure, including wearable-technology devices. Time taken to complete each assessment. Location and attendance at treatment sessions; content covered in treatment sessions; feedback from qualitative interviews; treatment acceptability score (AARP). Service use data completeness, time taken to collect service use data.
Secondary	Gather data on clinical outcomes to provide a preliminary indication of the clinical effectiveness of a novel sleep intervention (SleepWell) in addition to usual care versus usual care alone in young people with sleep problems who are at ultra-high-risk of psychosis attending NHS mental health services	Sleep disturbance: ISI; Sleep-50 CRD; Sleep diary; Actigraphy; Fatigue. Attenuated psychotic experiences: CAARMS; SPEQ-H; R-GPTS; ČEFSA. Psychiatric symptoms: DASS-21; C-SSRS; DWQ; BCSS. Activity and social functioning: Time budget; WASA; Oxford Agoraphobic Avoidance Scale; actigraphy. Physical health: BMI; step-count; BESAA; PHQ15; MAP. Quality of life: QPR; ReQoL; EQ5D. Service use: CSRI; and medication. Participant ranking of clinical outcome variables.
Qualitative	To explore the acceptability of study procedures to service users.	Feedback from qualitative interviews.

AARP, Abbreviated Acceptability Rating Profile; BCSS, Brief Core Schema Scale; BESAA, Body Esteem Scale for Adults and Adolescents; CAARMS, Comprehensive Assessment of At-Risk-Mental States; CRD, Circadian Rhythm Disruption; CSRI, Client Service Receipt Inventory; C-SSRS, Columbia Suicide Severity Rating Scale; DASS-21, Depression, Anxiety, and Stress Scale; DWQ, Dunn Worry Questionnaire; ČEFSA, Černis Felt Sense of Anomaly Scale; ISI, Insomnia Severity Index; MAP, Maudsley Addiction Profile; NHS, National Health Service; PHQ15, Patient Health Questionnaire; QPR, Process of Recovery Questionniare; R-GPTS, Revised Green et al Paranoid Thoughts Scale; SPEQ-H, Specific Psychotic Experiences Questionnaire - Hallucinations subscale; WASA, Work and Social Adjustment Scale.

establish the key parameters for a definitive RCT. The secondary research objective is to gather data on clinical outcomes to provide a preliminary indication of the clinical efficacy of the sleep intervention (SleepWell) for young people attending National Health Service (NHS) mental health services with sleep problems who are at ultra-high-risk of psychosis. Table 1 provides a summary of the objectives (and the associated feasibility markers or assessment measures).

Our hypotheses related to clinical outcomes are:

1. Compared with usual care, the SleepWell therapy added to usual care will reduce insomnia and other sleep disruption (post-treatment).
2. Compared with usual care, the SleepWell therapy added to usual care will reduce psychotic experiences (a key marker of psychosis risk) and rates of transition to psychosis (post-treatment).
3. Compared with usual care, the SleepWell therapy added to usual care will reduce psychiatric symptoms (depression, anxiety, worry, suicidal ideation), increase activity and social functioning, improve physical health, and enhance quality of life (post-treatment).
4. Treatment effects will be maintained at follow-up.

METHODS AND ANALYSIS

Trial design and flow chart

The design is a prospective, parallel group, single blind, randomised controlled feasibility trial to evaluate a novel sleep intervention (SleepWell) in addition to usual care versus usual care alone in young people with sleep problems who are at ultra-high-risk of psychosis and attending NHS mental health services. Standard care will be measured, but remain as usual in both groups. Assessments will be carried out at 0 (baseline), 3 (post-treatment) and 9 (follow-up) months by a researcher blind to treatment allocation. An embedded qualitative study will explore the acceptability of study procedures to participants. A summary of the trial design can be seen in figure 1. The trial is prospectively registered with the ISRCTN registry: ISRCTN85601537. There is a trial Data Monitoring and Ethics Committee (DMEC) and Lived Experience Advisory Panel (LEAP). The LEAP is facilitated by the McPin Foundation.

Randomisation, blinding and code-breaking

Participants will be randomised once they have completed the baseline assessment. Participants will be allocated to one of the trial arms using a 1:1 allocation

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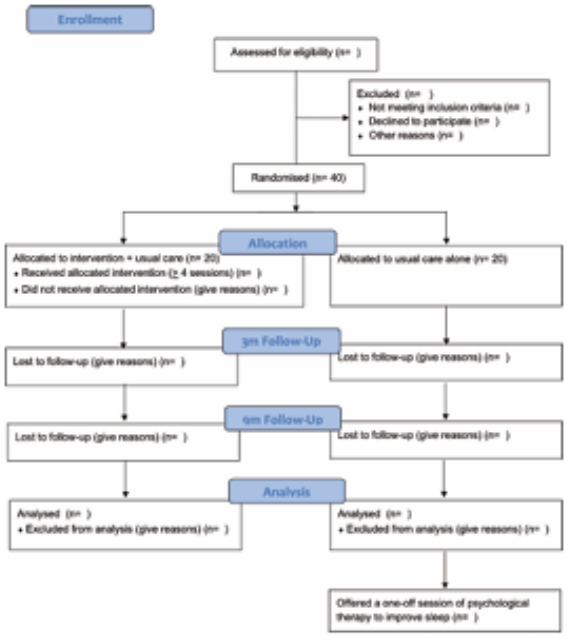

Figure 1 Trial flow diagram.

ratio. Randomisation will be carried out by a validated online system, Sortition, designed by the University of Oxford Primary Care Clinical Trials Unit. Allocation will be carried out using a non-deterministic minimisation algorithm to ensure balance across groups with respect to severity of sleep disturbance (Insomnia Severity Index (ISI) score ≤21/≥22) and referring service (early intervention in psychosis team (EIP), child and adolescent mental health services (CAMHS), improving access to talking therapies service (IAPT)).

The research assessor will be blinded to group allocation, but the patients and clinician delivering the intervention will not be (they cannot be blinded to whether a psychological intervention is delivered or received). If an allocation is revealed between assessment sessions, this is logged by the trial coordinator and future assessments conducted, where possible, by another assessor to re-establish the blind.

Participants

The trial participants will be 40 young people (aged 14 to 25 years) attending NHS mental health services with sleep problems who are at ultra-high-risk of psychosis. The principal method of recruitment will be via seeking referrals from the relevant clinical teams in the participating NHS mental health trusts. The services include specialist early intervention in psychosis services (EIP: ages over 14 years), child and adolescent mental health services (CAMHS: ages 0 to 18 years) and improving access to psychological therapies services (IAPT: ages over 18 years). The study will be advertised within participating NHS trusts and on social media so that young people receiving care in the recruiting NHS trusts can self-initiate referral to the trial. With the approval of the clinical team, all young people interested in taking part will then be approached by the research team, given information about the trial, and the screening conducted. The importance of self-initiated referral was highlighted by our LEAP to ensure accessibility and inclusivity. Informed consent will be obtained from all patients before participation.

Inclusion criteria

- Aged 14 to 25 years;
- Patient of mental health services (at the time of referral to the study);
- Meet diagnostic criteria for ultra-high-risk of psychosis on the Comprehensive Assessment of At-Risk-Mental-States (CAARMS);[30]
- Experiencing current sleep problems (defined as a score >15 on the Insomnia Severity Index (ISI)[31]);
- Would like help to improve sleep; and
- Willing and able to give informed consent (or assent with parent/guardian consent for participants aged 14 to 15 years) for participation in the trial.

Exclusion criteria

- Diagnosis of a primary severe mental health problem (including psychosis, bipolar disorder, personality disorder);
- Likely primary diagnosis of sleep apnoea (established using the STOP-BANG screen[32]);
- A primary diagnosis of alcohol or substance disorder;
- Organic syndrome;
- Significant learning disability; or
- Current engagement in any other individual psychological therapy.

Assessments

Basic demographic and clinical data will be collected (eg, age, gender, ethnicity, clinical diagnosis). Clinical outcomes including sleep disturbance, psychotic and affective symptoms, social functioning, quality of life and physical health will be assessed at all three time points (baseline 0 months, post-intervention 3 months and follow-up 9 months).

Insomnia (ISI),[31] circadian rhythm disruption (SLEEP-50 CRD subscale[33]) and fatigue[34] will be assessed via self-report. Sleep and activity levels will also be assessed using actigraphy (over 7 days), complemented with sleep diaries and a time-budget assessing meaningful activity.[35]

Attenuated psychotic symptoms and transition to psychosis (Comprehensive Assessment of At-Risk-Mental-States (CAARMS)[30]), hallucinatory experiences (Specific Psychotic Experiences Questionnaire – Hallucinations subscale (SPEQ-H)[36]), paranoia (Revised-Green *et al* Paranoid Thoughts scale (R-GPTS)[37]) and dissociative experiences (Černis Felt Sense of Anomaly Scale (ČEFSA)[38]) will be assessed.

Levels of depression and anxiety (Depression, Anxiety and Stress Scale (DASS-21)[39]), worry (Dunn Worry

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Questionnaire (DWQ)[40]), suicidal ideation (Columbia Suicide Severity Rating Scale (C-SSRS)[41]) and self-concept (Brief Core Schema Scale (BCSS)[42]) will be measured.

Social functioning will be assessed using the Work and Social Adjustment Scale (WASA)[43] and Oxford Agoraphobic Avoidance Scale.[44] The Process of Recovery Questionnaire (QPR),[45] EQ-5D-5L (http://www.euroqol.org/) and ReQol[46] will assess quality of life.

Body mass index (BMI), somatic symptoms (Patient Health Questionnaire 15 (PHQ15)[47]), appearance concerns (Body Esteem Scale for Adults and Adolescents (BESAA)[48] and substance use (Maudsley Addiction Profile (MAP)[49]) will be measured as markers of physical health. Service use, and other relevant health economic data, will be recorded using the Client Service Receipt Inventory (CSRI).[50]

A qualitative interview will be conducted with a subset of 16 participants (n=10 intervention, n=6 control) after their final assessment. The semi-structured interview will explore participants' experiences of therapy and trial participation.

The SleepWell intervention

SleepWell is a psychological intervention designed for young people that targets the key mechanisms which regulate sleep: circadian rhythm, sleep pressure, and hyperarousal.[51–53]

1. To target circadian rhythm, the timing of sleep, we use light/dark exposure which is the key zeitgeber or time cue for sleep, to re-align sleep patterns with the environment. We also re-establish circadian rhythms using daily activity points.
2. To target sleep pressure, the need for sleep, we increase daytime activity to increase night-time tiredness. We use the motivational benefits of fitness-trackers.
3. To target hyperarousal, which can disrupt sleep despite circadian entrainment and high sleep pressure, the key strategy is stimulus control which enables patients to relearn the association between bed and sleep. We also use worry reduction strategies, cognitive restructuring techniques, and night-time relaxation.

SleepWell has been specifically designed with consideration of the unique aspects of sleep in youth, such as the biological changes in sleep architecture (eg, delayed sleep-phase) and lifestyle factors (eg, exam pressures, increasing independence). For example, SleepWell includes the use of technology-devices, engaging family/friends to support the young person, and adaptations of stimulus control due to environmental constraints such as shared accommodation at university.

The SleepWell intervention is manualised in a modular format. The five core modules include: (1) psychoeducation, assessment and goal setting (eg, actigraphy data are used to monitor sleep patterns and identify foci for change); (2) establishing the environmental and lifestyle context for sleep; (3) stimulus control and strategies to reduce hyperarousal; (4) circadian entrainment (using light/dark exposure, setting the sleep window, boosting zeitgebers, for example, meal and activity times); and (5) relapse prevention. Additional modules are selected by patients on the basis of individual need, enabling the intervention to be personalised to the individual's needs (eg, night-time worry). The format and manuals have been developed in collaboration with our LEAP.

The intervention is delivered by a clinical psychologist, on an individual basis in up to eight 1-hour sessions. There is typically one session per week. Additional contact between sessions (eg, text messages, email) is provided to support treatment strategy implementation. A treatment dose is defined as four or more sessions. In line with the International Early Psychosis Association recommendations that interventions are provided flexibly and in low stigmatising environments, sessions are held in the patient's home or local health service clinic.[54] At the final session, participants will be asked to complete a self-report questionnaire to assess the acceptability of the intervention (AARP[55]).

SleepWell will be provided in addition to usual care. With patient consent, sessions will be audio-recorded and independently rated for quality, including fidelity and competence.

Control condition

Participants who are allocated to the control arm will continue to receive their usual care. Treatment as usual for the participants in this trial will typically consist of monitoring meetings with a general practitioner or mental health practitioner and psychiatric medication (as needed). Treatment as usual will vary across individuals, clinical teams and mental health trusts. We will collect detailed data on treatment as usual (which will also inform the preliminary health economic evaluation).

At the end of their participation in the study, participants in the control arm will be offered a one-off session about sleep with a clinical psychologist. This session will briefly identify a plan to improve sleep, which participants may then implement independently. The LEAP emphasised the importance of offering this session.

Adverse events

A serious adverse event (SAE) is defined as any untoward medical occurrence that results in death, is life threatening, requires or prolongs hospitalisation or results in persistent or significant disability/incapacity. The sorts of SAEs that can typically occur in this participant group include: deaths, suicide attempts, serious violent incidents, and admissions to hospital. Hospitalisation for a pre-existing physical health condition, including elective procedures planned prior to study entry, which has not worsened, does not constitute an SAE.

A trial standard operational procedure has been written for adverse events. We will record the occurrence of any SAEs reported to us and also systematically check all participants' medical records following completion of the final assessment. We will also record transition to psychosis and formal complaints regarding therapy. Transition to

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psychosis will be determined through multiple sources including: scoring above psychosis threshold on the CAARMS[50] at the research assessments; review of medical records; clinical team feedback; prescription of antipsychotic medication, and the clinical observation of the study therapist. The responsible clinical team, the trial management committee and the DMEC will be informed of any adverse event.

Analysis

A full statistical analysis plan will be drafted prior to recruitment beginning and finalised before any analysis takes place. There are no interim analyses or formal stopping rules in relation to this study as the primary goal is to establish feasibility parameters for a definitive trial. Data will be reported in line with the CONSORT 2010 Statement, SPIRIT and GRIPP2 guidelines.

Analysis will be descriptive in nature and no hypothesis testing will be carried out. The number (percentage) will be presented for feasibility measures (ie, recruitment and retention, uptake of treatment, data completion) overall and by randomised group. Progression criteria related to key feasibility outcomes such as recruitment, retention, and treatment uptake rates have been identified. These criteria outline the potential progression from feasibility to definitive trial. Each criterion has 'stop/amend/go' indicators. For example, the progression criterion for treatment uptake will be: 75% and above indicates the progression criterion has been met, 51% to 75% indicates the need to amend, and below 50% indicates stop.

The patient outcome measures will be described using the mean (SD) or median (IQR) depending on the distribution of the measure and by the number (percentage) for binary outcomes. At baseline, patient measures will be reported overall and by randomised group. At follow-up points, patient outcomes will be presented by randomised group and the difference between groups and 95% CI for the difference will be reported to aid sample size calculations for the definitive trial.

The primary aim of this feasibility trial is to establish the necessary parameters for a definitive trial. This includes recruitment, retention, and treatment uptake rates. A sample size of 20 per randomised group (40, in total across the study) will be sufficient to estimate a recruitment rate of 50% with a 95% CI of 35% to 65% and a retention rate of 80% with a 95% CI of 65% to 90% (PASS V.12). This sample size of 20 per arm will be sufficient to estimate the variability of outcome measures for future sample size calculations, with 12 per arm sufficient for estimation of the variability for the purpose of sample size calculations.[56]

All participants recruited to the feasibility trial will be documented fully with respect to receiving the intervention and participating in follow-up. Although no formal statistical analysis will be undertaken, outcomes will be reported by randomised group for all participants randomised, irrespective of whether they received the intervention or not (intention-to-treat). Adverse events will be reported for all participants randomised.

A microcosting approach will be used to inform the cost per patient of the SleepWell intervention. As part of this feasibility study, we will determine the acceptability and completeness of the necessary data (CSRI, medication use, ReQOL and EQ-5D) to perform a full health economic analysis. Further to this we will investigate the possibility of developing a decision-analytical model that would permit the generation of cost-effectiveness estimates in the long-term (eg, costs and outcomes in patient's lifetime) based on a large evaluation trial of the SleepWell intervention.

The qualitative interviews will be recorded, transcribed verbatim, and analysed using Thematic Analysis.[57] This includes the identification of codes, candidate themes and thematic map. A thematic map reflects the meanings of the overall data set and provides a conceptualisation of the themes and relationships between them. Quality guidelines[58 59] will be followed, including credibility checks and reflexive practice.

Patient and public involvement

Patient and Public Involvement is being facilitated by The McPin Foundation, a charity that exists to 'put the lived experience of people affected by mental health problems at the heart of research' (www.mcpin.org). A grant holder is from The McPin Foundation. The application was developed in collaboration with young people with experience of sleep problems and psychosis. Following the award of the grant, a fully funded LEAP has been formed to advise on all stages of the research programme (for example, participant recruitment, analysis of the qualitative interview data and dissemination of the research findings). The LEAP will meet throughout the course of the trial.

For the trial protocol, the LEAP has advised on: the length of follow-up period, the age range of participants, the choice of outcome measures, recruitment methods, the format of recruitment materials and the content and wording of study materials (including the information sheet, consent/assent form, and therapy manuals). The LEAP has also reviewed and commented on the trial protocol document.

Ethics and dissemination

The trial has received Health Research Authority (HRA/HCRW) approval (IRAS 281235, The SleepWell trial). The trial received ethical approval from the NHS South Central - Oxford A Research Ethics Committee (20/SC/0281). R&D teams at participating NHS trusts will confirm local capacity and capability to deliver the research. The University of Oxford is the trial sponsor. The results of the trial will be published in a peer-reviewed journal and made open access. An anonymised version of the main outcome data will be available from the trial team on reasonable request after publication of the main results paper. A summary of the results, developed

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in collaboration with the LEAP, will be provided to all participants.

Trial status

The trial is due to start patient recruitment in November 2020. Recruitment will be for 14 months until January 2022, with final outcome data collected by September 2022. A trial paper detailing the outcomes should be submitted for publication around December 2022.

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Sleep and schizophrenia: From epiphenomenon to treatable causal target

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ABSTRACT

Background: Sleep disturbance is a common clinical issue for patients with psychosis. It has been identified as a putative causal factor in the onset and persistence of psychotic experiences (paranoia and hallucinations). Hence sleep disruption may be a potential treatment target to prevent the onset of psychosis and reduce persistent psychotic experiences. The aim of this review is to describe developments in understanding the nature, causal role, and treatment of sleep disruption in psychosis.

Method: A systematic literature search was conducted to identify studies, published in the last five years, investigating subjective sleep disruption and psychotic experiences.

Results: Fifty-eight papers were identified: 37 clinical and 21 non-clinical studies. The studies were correlational ($n = 38$; 20 clinical, 18 non-clinical), treatment ($n = 7$; 1 non-clinical), qualitative accounts ($n = 6$ clinical), prevalence estimates ($n = 5$ clinical), and experimental tests ($n = 2$ non-clinical). Insomnia (50%) and nightmare disorder (48%) are the most prevalent sleep problems found in patients. Sleep disruption predicts the onset and persistence of psychotic experiences such as paranoia and hallucinations, with negative affect identified as a partial mediator of this relationship. Patients recognise the detrimental effects of disrupted sleep and are keen for treatment. All psychological intervention studies reported large effect size improvements in sleep and there may be modest resultant improvements in psychotic experiences.

Conclusions: Sleep disruption is a treatable clinical problem in patients with psychosis. It is important to treat in its own right but may also lessen psychotic experiences. Research is required on how this knowledge can be implemented in clinical services.

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1. Introduction

> "When I'm tired, everything is worse"
> (Patient with psychosis, Waite et al., 2016a, p.186)

Since the first descriptions of schizophrenia sleep dysfunction has been a feature of patient, family, and clinician accounts (see Kraeplin, 1919; Birchwood et al., 1989; Yung and McGorry, 1996). Despite this, sleep problems have been overlooked as a treatment target. Historically, sleep disruption has been seen as a non-specific epiphenomenon or secondary consequence of a core psychotic disturbance. Over the past ten years there has been increasing interest in a different view: that sleep dysfunction may be a potential causal mechanism in the onset and persistence of psychotic experiences (Anderson and Bradley, 2013; Freeman et al., 2009; Reeve et al., 2015; Soehner et al., 2013; Waters et al., 2017). This paradigm shift identifies sleep disruption as a potential novel treatment target for psychotic symptoms. It also provides a route to determine causality: if successful treatment of sleep problems results in improvements in psychotic experiences then a causal relationship is demonstrated. Our previous review found that sleep disturbance and psychotic experiences co-occur (Reeve et al., 2015), but the direction of effect and underlying mechanisms were yet to be established. Given the recent work on sleep and psychosis, particularly treatment innovation, it is timely to review the current status of the evidence and consider the implications for clinical practice.

In patients with psychosis sleep problems are very common. For example, in a survey of 1809 patients with non-affective psychosis attending NHS mental health services, 50.1% had clinically significant levels of insomnia (Freeman et al., 2019). Disturbances in sleep architecture and circadian systems are also typically found in patients (Cosgrave et al., 2018). Indeed the clinical picture is complex, with comorbidity of sleep disorders normal rather than the exception (Reeve et al., 2019b). Patient accounts highlight an interaction between sleep difficulties and psychotic experiences and describe the negative impact on

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functioning (Faulkner and Bee, 2017; Waite et al., 2016a; Waite et al., 2018). Clinicians certainly recognise the prevalence and importance of sleep problems, but in current practice formal assessment infrequently occurs and the provision of recommended treatment is extremely limited (Rehman et al., 2017; Reeve et al., 2019b). Yet there is a clear desire for treatment: three-quarters of patients with psychosis who have insomnia would like treatment to improve their sleep (Freeman et al., 2019).

In international guidelines the recommended first line treatment for insomnia is cognitive behavioural therapy (CBTi) (for example, National Institute for Health and Care Excellence, 2015; Qaseem et al., 2016; Wilson et al., 2019). CBTi targets the subjective sleep disturbance which characterises insomnia. It has a well-established evidence base demonstrating effectiveness in treating insomnia (without comorbid psychosis), for example a recent meta-analysis of 87 randomised controlled trials (RCT) found large effect size improvements in self-reported insomnia symptoms (hedges g = 0.98) (van Straten et al., 2018). In recent years, researchers have begun to investigate the applicability, feasibility, and effectiveness of CBTi in people with psychotic experiences in the general population (Freeman et al., 2017), individuals at ultra-high-risk of psychosis (Bradley et al., 2018, patients with persistent psychotic experiences (e.g. Freeman et al., 2015; Hwang et al., 2019; Chiu et al., 2018;) and patients admitted to acute psychiatric inpatient care (Sheaves et al., 2018a). This review aims to provide an overview of sleep disruption and its treatment across this spectrum of psychosis severity. Given previous reviews on the occurrence of sleep disruption and its contribution to psychotic experiences (see Cosgrave et al., 2018; Davies et al., 2017; Reeve et al., 2015) the main focus of this review will be on treatment developments in the past five years. Consistent with treatment guidelines this review will focus on evidence-based psychological interventions. By conducting a literature review of the studies published in the last five years investigating sleep disruption and psychotic experiences, we sought to address the following questions:

1. What is the experience of sleep disruption and its treatment in patients experiencing psychotic symptoms?
2. Do subjective sleep disturbance and psychotic experiences co-occur across this spectrum of psychosis severity?
3. Are psychological interventions for sleep disturbance (CBT) applicable, feasible, and effective on a) subjective sleep problems, b) psychotic experiences?

2. Method

A search was carried out on PubMed for English language papers published in peer-reviewed journals containing the following terms: ((sleep OR insomnia OR dream* OR nightmare*) AND (Delus* OR Hallucinat* OR Psychosis OR *Schizophren* OR Schizotyp*)), published in the last five years (search conducted on 5th August 2019). Literature on non-human studies was not included. The search criteria were consistent with our earlier review (Reeve et al., 2015) to enable a focus on recent findings.

Both qualitative and quantitative methodologies were included. Papers relating primarily to dementias or other neurological conditions, bipolar disorder, or affective psychoses (including post-partum psychosis) were excluded. Previous reviews were excluded. For quantitative studies, a specific measure of subjective sleep disturbance was required. There are elevated rates of obstructive sleep apnea in patients with psychosis (24%) (see Annamalai et al., 2015) and an established respiratory treatment, however this is outside the scope of this review.

This search revealed 789 papers. Titles and abstracts were scanned, and if appropriate the whole paper, in order to ascertain the inclusion and exclusion criteria. The reference lists of relevant papers were also scanned for further citations, which provided an additional 11 papers. See Fig. 1 for a PRISMA flow diagram of the systematic review process.

3. Results

Fifty-eight papers were included in the review. Thirty-seven papers concerned clinical samples (8 ultra-high-risk, 3 first-episode psychosis, 22 schizophrenia, 4 acute inpatients) and 21 concerned non-clinical samples. Within the clinical samples there were six qualitative studies, five studies assessed the prevalence of sleep disturbance, 20 studies provided correlational data, and six studies evaluated psychological treatment. In the non-clinical studies, 18 studies provided correlational data, two were manipulation tests, and one study concerned treatment.

3.1. The patient experience of sleep disruption and its treatment

> *"…because, the voices, and there's too many things on your mind and you get anxious and stuff like that but it's…yeah, it is quite hard to get to sleep, it's stressful."* (patient 15; Faulkner and Bee, 2017)

> *"When I'm tired it gets worse because I don't have the strength to fight the voices as much"*. (patient 1; Waite et al., 2016a)

Across the spectrum of severity of psychosis there is a striking consistency in patient accounts of the nature of sleep disturbance, the interaction with psychotic experiences, the negative impact on functioning, and treatment preference (Chiu et al., 2016; Faulkner and Bee, 2017, 2016; Waite et al., 2016a; Waite et al., 2018; Waters et al., 2015).

Patients describe how sleep can be disrupted by psychotic experiences, for example: "if I'm having voices and stuff I find it harder to sleep, my mind's racing" (3, Chiu et al., 2016); "These voices like to see me awake and agitated." (13, Faulkner and Bee, 2017). Patients also highlight the reverse: that sleep problems contribute to the occurrence of psychotic experiences. Indeed, patients describe the reciprocal nature of sleep problems and psychotic experiences as a "nightmare you can't get out of" (4, Waite et al., 2016a). Yet this also indicates a self-identified avenue for improvement: "sometimes my voices would be better as well from sleeping" (2, Waite et al., 2016a). In young people at ultra-high-risk of psychosis, sleep disturbance was typically characterised by disrupted sleep timing (Waite et al., 2018). In contrast, patients with persistent psychotic experiences often described being reliant on hypnotic medication or using neuroleptic medication as a route to initiate sleep: "knocking yourself out" (Faulkner and Bee, 2017, p.8).

Despite wanting better sleep, the accounts highlight a sense of hopelessness and limited expectation concerning treatment outcome. There were often beliefs that sleep simply cannot be changed: "I just seem to be at the mercy of it you know. I just don't really have any control over it really. It's just sometimes it happens for me, and sometimes it doesn't." (5, Chiu et al., 2016). This sense of resignation was more profound in patients with persistent psychosis, for example: "I know I'm going to be like this forever, there's no point in telling a lie to myself, I know I'll always have problems sleeping" (2, Faulkner and Bee, 2017). Yet it was already present in many young people at ultra-high-risk of psychosis when offered a sleep intervention: "I didn't think it would work at first" (8, Waite et al., 2018).

Those patients who had received a psychological sleep intervention described important clinical change and valuing the therapy: "It was really, really good. Really good. I was really impressed. I didn't think it was going to help or anything. I am really impressed" (10, Waite et al., 2016a). For some, the process of implementing new strategies was challenging: "It's hard to try and change, to try and get myself motivated" (7, Waite et al., 2018). Yet, for others, treating sleep problems was identified as a route to improving wider mental health. With some patients explicitly describing an improvement in psychotic symptoms with

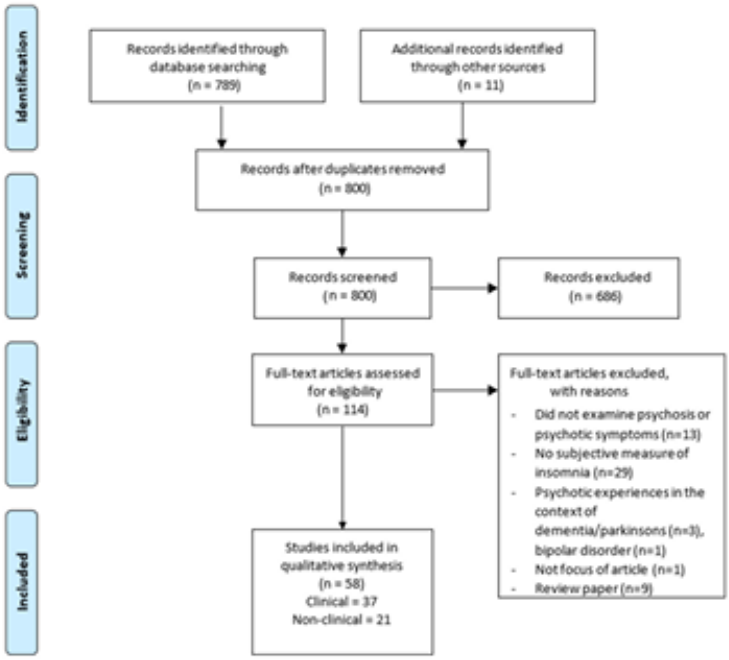

Fig. 1. PRISMA flow diagram of the systematic review process.

improved sleep: "since I've been sleeping better, my, visual things have like stopped" (8, Waite et al., 2018).

3.2. The prevalence of sleep disturbance in patients

The patient accounts of sleep disturbance are consistent with the empirical data. Rates of sleep disturbance are elevated across the spectrum of severity of psychotic experiences. Studies indicate that 75–80% of patients at ultra-high-risk (Poe et al., 2017), those who have experienced a first episode (Ma et al., 2018; Reeve et al., 2019b), and patients with a diagnosis of schizophrenia (Laskemoen et al., 2019) are experiencing subjective sleep disturbance. There were no studies in the past five years reporting prevalence in acute settings. When specific sleep disorders are assessed using self-report or clinician interview measures the rate of insomnia is approximately 50% (Freeman et al., 2019; Laskemoen et al., 2019), the rate of weekly nightmares 55% (Sheaves et al., 2015), and the rate of hypersomnia 30% (Laskemoen et al., 2019) in patients with non-affective psychosis. Only one study has conducted formal diagnostic sleep interviews in patients with psychosis (Reeve et al., 2019b). In a sample of 60 patients with early psychosis, insomnia (50%) and nightmares (48%) were the most common disorders. Sleep disorders were not only highly prevalent but frequently comorbid: the average number of sleep disorders per patient was 3.3 (Reeve et al., 2019b).

3.3. Sleep disturbance as a causal factor for psychotic experiences

3.3.1. Correlational data

Our previous review found a robust association between sleep dysfunction and psychotic experiences (Reeve et al., 2015), especially between insomnia and paranoia. The current review found 38 recent studies: 18 general population (Table 1) and 20 clinical samples (Table 2) reporting an association between sleep disruption and psychotic experiences.

3.3.1.1. General population studies. The findings from these recent studies robustly confirm the cross-sectional association between sleep dysfunction and psychotic experiences. For example, an analysis of data from over a quarter of a million people in the general population found that insomnia significantly increased the likelihood of reporting at least one psychotic symptom (OR = 2.41; 95% CI 2.18–2.65) (Koyanagi and Stickley, 2015). In addition to the evidence for insomnia, an online study with 846 participants from the general population found that, even after controlling for PTSD and negative affect, both nightmare occurrence and severity were associated with hallucinatory experiences and paranoia (Rek et al., 2017).

Several studies provide insight into the temporal relationship using longitudinal and experience sampling method (ESM) designs. For example, in a sample of 4720 young people, nightmares at age 12 predicted psychotic-like experiences (PLE) at age 18 (OR = 1.62, 95% CI 1.19–2.20) (Thompson et al., 2015). In an ESM study of 61 adolescents, shorter sleep duration predicted paranoia, but paranoid symptoms did not predict sleep parameters (Hennig and Lincoln, 2018).

Within correlational studies, a number of potential mechanisms have been investigated. For example, an online study with 2678 students found that depression and PTSD symptoms, but not anxiety symptoms, mediated the relationship between poor sleep and PLEs (Ered et al., 2018). This study examined positive symptoms, but did not report the findings for individual psychotic experiences. Structural equation modelling of a sample of 348 students, recruited in an online study, found an association between subjectively delayed sleep onset and persecutory ideation that was fully mediated by negative affect (Scott et al., 2017). However there are obvious limitations of cross-sectional mediation analyses (see Maxwell and Cole, 2007). Mediation tests related to

Table 1
Non-clinical studies.

Reference	Design	Sample	n	Participant characteristics	Measure of sleep disturbance	Measure of psychotic experiences	Key finding
Meyhöfer et al., 2017	Manipulation (sleep deprivation) Within subjects design	General population	32	16 male (50%), mean age 23.97 years (SD = 3.46)	Sleep diary	PSI	Sleep deprivation induced psychosis-like experiences such as hallucinations, cognitive disorganisation and negative symptoms.
Reeve et al., 2018a	Manipulation (sleep restriction) Within subjects design	General population	68	46% male, mean age 22.5 years (SD = 3.4)	Sleep diary and actigraphy	SPEQ	Compared to the control condition, participants in the sleep loss condition reported significant increases in paranoia, hallucinations and cognitive disorganisation. Changes in psychotic experiences were mediated by changes in negative affect.
Andorko et al., 2018	Cross sectional	Students	409	49.4% male, mean age 20.10 years (SD = 3.22)	ISDI	PQ-B	Nightmares and fragmented sleep were both significantly associated with the presence of psychotic-like experiences.
Cosgrave et al., 2018	Cross sectional	Students	43	44.2% male, mean age 23.9 years, (SD = 3.6) in the control group and 22.8 years, (SD = 3.2) in the experimental group.	PSQI, ISI, actigraphy	PQ-16	Objective and subjective sleep measures interact to predict the highest risk of psychotic experiences. The combination of perceived poor sleep and actual lack of sleep predicts the greatest risk for psychotic experiences.
Ered et al., 2018	Cross sectional	Students	2687	26% male, mean age 20.22 years (SD = 3.21)	PSQI	PQ	The relationship between psychotic-like experiences and sleep quality was mediated by symptoms of depression and PTSD, suggesting that treating symptoms of depression and PTSD could improve multiple domains of psychotic illness.
Hennig and Lincoln, 2018	Cross sectional	Healthy volunteers (adolescents)	61	50.8% male, mean age 15.1 years (SD = 1.1)	Sleep diary and actigraphy	Six items from the SPEQ	Shorter sleep duration and more dreaming predicted paranoid symptoms, but paranoid symptoms did not significantly predict sleep parameters. Positive and negative affect partially mediate the effect of sleep duration on paranoid symptoms.
Peña-Falcón et al., 2019	Cross sectional	General population	177	35.6% male, mean age 31.17 years (SD = 12.85)	PSQI, Iowa sleep experiences survey	Launay–Slade Hallucination Scale-revised, DES.	There was a significant positive association between quality of sleep and hallucination proneness, dissociation and unusual sleep experiences. Sleep quality and hallucination proneness was fully mediated by dissociation and unusual sleep experiences.
Rehman et al., 2018	Cross sectional	General population (healthy volunteers)	Study 1, 401; study 2, 402	Study 1: 23.2% male, mean age 24 (SD = 8.1); Study 2: 28.4% female, mean age 24 years (SD = 10.8)	PSQI	GPTS-B; CAPS.	Study 1: The relationship between sleep quality and paranoia was partially mediate by alexithymia, perceptual anomalies and negative affect. Study 2: The relationship between sleep quality and paranoia was fully mediated by negative affect, perceptual anomalies and alexithymia.
Andorko et al., 2017	Cross sectional	Students	409	49.1% male, mean age 20.09 years (SD = 3.22)	ISDI	PQ-B	Fragmented sleep, night anxiety and disturbed sleep all significantly correlated with psychotic-like experiences.
Moritz et al., 2017	Longitudinal	General population	2357	40.8% male, mean age 46.9 years (SD = 14.5)	PHQ-9	18-item PCL	Paranoia predicted sleep dysfunction six months later, but not the reverse.
Rek et al., 2017	Cross sectional	General population	846	11% male, mean age 44 years (SD = 15.9)	NSS, ISIS, MCTQ	SPEQ, CDS	When controlling for negative affect, nightmare occurrence was associated with high levels of worry, depersonalisation, hallucinatory experiences, paranoia, and sleep duration. Nightmare severity was associated with higher levels of worry, depersonalisation, hallucinatory experiences, and paranoia.
Scott et al., 2017	Cross sectional	General population	389	24% male, mean age 36.49 (SD = 12.76)	8-item insomnia subscale of the Sleep-50 questionnaire	GPTS-B, DASS-21	The findings point to an association between perceived (but not objective) difficulties initially falling asleep (but not maintaining sleep) and paranoid thinking; a relationship that is fully mediated by negative affect.
Oh et al., 2016	Cross sectional	General population (national	2304	Gender and age not reported.	DSM-IV criteria for sleep disturbance	WHO-CIDI 3.0 Psychosis Screen	People with sleep disturbances lasting 2 weeks or more over the past 12 months were significantly more likely to report at least one

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Table 1 (continued)

Reference	Design	Sample	n	Participant characteristics	Measure of sleep disturbance	Measure of psychotic experiences	Key finding
		epidemiological survey)					psychotic experience over the same time frame, when compared to people without any sleep problems.
Sheaves et al., 2016a	Cross sectional and longitudinal	General population (two national epidemiological surveys)	2000 dataset: 8580 2007 dataset: 7403 Longitudinal dataset: 2406	2000 dataset: 46.8% male, mean age 43.87 (SD = 0.23) 2007 dataset: 48.6% male, mean age 46.35 (SD = 0.03) Longitudinal dataset: 49.3% male, mean age: 43.44 (SD = 0.49)	Clinical Interview (CIS-R)	PSQ	Insomnia was associated with hallucinations in both cross-sectional datasets. Mild sleep problems were associated with 2–3 times greater odds of reporting hallucinations, whilst chronic insomnia was associated with four times greater odds. These associations remained significant, although with smaller odds ratios, after controlling for depression, anxiety and paranoia.
Sheaves et al., 2016b	Cross sectional	Undergraduate and postgraduate students	1403	44.4% male Median age: 21 (interquartile range = 20–23)	SCI, retrospective Dream Log (adapted from Levin and Fireman), MCTQ, SJL.	SPEQ, DASS-21.	Insomnia, nightmares, and circadian phase delay are associated with increased subsyndromal psychiatric symptoms in young people. Each is a treatable sleep disorder and might be a target for early intervention to modify the subsequent progression of psychiatric disorder.
Chung et al., 2015	Longitudinal cohort	General population (Taiwan's National Health Insurance Research Database)	30,670	41.1% male, age reported by subgroups	Diagnosis of insomnia, prescription for sedative-hypnotics at a defined daily dose of at least 30 per year.	Diagnosis of psychiatric disorder.	People with insomnia taking sedative-hypnotic prescriptions had an elevated risk of developing psychiatric disorders compared to those without insomnia or a sedative-hypnotic prescription.
Jeppesen et al., 2015	Cross sectional	11–12 year old population cohort sample (Copenhagan child cohort 2000)	1632	Gender and age not reported.	Self-reported sleep problems and patterns in a structured interview.	K-SADS-PL-semi structured interview.	Sleep problems increased the risk of psychotic experiences, after controlling for gender, puberty and other mental disorders. Psychotic experiences are particularly prevalent in the context of sleep disturbance and affect dysregulation.
Koyanagi and Stickley, 2015	Cross sectional	General population (WHO epidemiological survey including 70 countries)	26,1547	Gender and age reported by country.	Single question problem sleeping (falling asleep, waking up frequently, or too early), 5-point scale (none -extreme).	CIDI 3.0 positive psychotic symptoms.	Sleep problems associated, in a dose-response fashion, with psychotic symptoms in almost all countries.
Taylor et al., 2015	Cross sectional	16 year old twin pairs from population cohort (TEDS)	5076 pairs of twins	53% male, age 16 years	PSQI, ISI	SPEQ	Shared genetic and environmental mechanisms for psychotic experiences and sleep disturbance. Association remained after controlling for negative affect.
Thompson et al., 2015	Longitudinal.	18 year old population cohort sample (ALSPAC)	4720	43.5% male (n = 2666) and age 18 years	Postal questionnaire (completed by mother) at age2.5, 3.5, 4.75, 6.75, 9 years. Experience of nightmares, night terrors and sleepwalking was assessed using a semi-structured interview at age 12 years.	PLIKSi at age 12 and 18 years.	Nightmares at 12 were a significant predictor of psychotic experiences at 18, remained after adjustment for possible confounders and psychotic experiences at 12 years.

Table 1 key: CAPS = Cardiff anomalous perceptions scale; CDS = Cambridge depersonalisation scale; CIS-R = Clinical interview schedule - revised; DASS-21 = Depression, anxiety, and stress scale; DES = Dissociative experience scale; GPTS = Green paranoid thoughts scale; ISDI = Iowa sleep disturbances inventory; ISI = Insomnia severity index; MCTQ = Munich chronotype questionnaire; NSS = Nightmare severity scale; PCL = Paranoia checklist; PHQ-9 = Patient health questionnaire; PLIKSi = Psychosis-like symptoms semi-structured interview; PSI = Psychotomimetic states inventory; PQ = Prodromal questionnaire (PQ-B brief; PQ-16 version); PSQ = Psychosis screening questionnaire; PSQI = Pittsburgh sleep quality index; SCI = Sleep condition indicator; SJL = Social Jet Lag; SPEQ = Specific psychotic experiences questionnaire.

Table 2
Correlational studies with clinical samples.

Reference	Design	Sample	n	Participant characteristics	Measure of sleep disturbance	Measure of psychotic experiences	Key finding
Goines et al., 2019	Longitudinal	Youth with clinical high risk (CHR)	1020	CHR (n=740), Gender (male = 424), Age (m = 18.5, SD = 4.26). HC (n=280), Gender (male = 141), Age (m = 19.7, SD = 4.67).	SOPS (G1 Sleep Item).	SIPS, SOPS	Positive association between sleep problems and attenuated psychotic symptom severity. Sleep problems closely associated with suspiciousness. Depression mediated the cross-sectional association between sleep problems and paranoid symptoms only.
Reeve et al., 2019b	Longitudinal	Individuals at risk of psychosis	160	Gender (male = 98), Age (m = 20.9, SD = 4.2).	Self-reported sleep duration from EPQ interview.	CAARMS	Association found between shorter sleep duration and increased positive symptoms, but not cognitive disorganisation. Longitudinal relationships did not remain significant when controlling for previous severity of psychotic symptoms.
Bird et al., 2017	Longitudinal, Observational	Help-seeking adolescents reporting paranoid thoughts.	34	Gender (male = 6), Age (m = 14.9, SD = 1.25).	ISI	GPTS, PANSS (suspiciousness/persecution item), SPEQ.	Insomnia found to be a significant predictor of paranoia persistence.
Lunsford-Avery et al., 2017a	Cross-sectional	Adolescents at ultra-high risk (UHR)	62	Gender (male = 37), Age (m = 18.93, SD = 1.67).	PSQI	SIPS, SCID	Self-reported sleep problems were associated with impaired procedural learning rate.
Lunsford-Avery et al., 2017b	Longitudinal	Adolescents with clinical high risk (CHR)	66	CHR (n=34), Gender (male = 15), Age (m = 18.79, SD = 1.93) HC Gender (male = 16), Age (m = 17.75, SD = 2.79)	Actigraphy, Sleep/Activity Diary	SIPS, SCID	In CHR participants, circadian disturbances were associated with psychotic symptom severity and predicted symptom severity and psychosocial impairment at 1-year follow-up.
Poe et al., 2017	Longitudinal	Help-seeking clinical high risk (CHR) patients.	260	CHR (n=194), Gender (male = 142), Age (m = 20.0, SD = 3.8). HC (n=66), (male = 42), Age (m = 21.9, SD = 3.6)	SIPS (G1 Sleep Items)	SIPS	Rates of sleep disturbance were significantly elevated in patients. Sleep disturbance was associated with increased positive and negative symptoms and worse overall functioning.
Lunsford-Avery et al., 2015	Longitudinal	Adolescents with ultra-high risk (UHR)	67	UHR (n=31), Gender (male = 19), Age (m = 18.73, SD = 1.89). HC (n=36), Gender (male = 16), Age (m = 17.85, SD = 2.62).	Actigraphy (TST, WASO, sleep efficiency and total movement counts), Sleep/activity diary, PSQI	SIPS, SOPS, SCID	Patients displayed reduced efficiency, disrupted continuity, and increased movements during sleep compared to HC. This behaviour was associated with increased positive symptoms at baseline.
Kasanova et al., 2019	Longitudinal (Experience sampling) Mediation analysis	Acutely paranoid patients with a psychotic disorder (AP), non-paranoid patients with a psychotic disorder (NP) and individuals with high schizotypy traits (ST).	115	AP (n = 42) NP (n = 32) ST (n = 41)	Momentary sleep quality: "I slept well last night" (7-point likert scale)	PANSS CAPE-42 Momentary paranoia (7-point likert scale)	Poor subjective sleep quality predicted elevated paranoia the following morning. This relationship was fully mediated by morning negative affect. No significant association between evening paranoia and poor sleep the following night emerged.
Chung et al.,	Cross-sectional	Outpatients with schizophrenia with	66	Gender (male =	Clinical interview using ICSD-3 criteria for delayed	PANSS	Sleep irregularity was associated with

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Table 2 (*continued*)

Reference	Design	Sample	n	Participant characteristics	Measure of sleep disturbance	Measure of psychotic experiences	Key finding
2018		delayed sleep-wake phase disorder and normal sleep-wake phase		30), Age (m = 44.08, SD = 12.64).	sleep-wake phase disorder. Actigraphy, The consensus sleep diary, CSM, PSQI, ESS		positive psychotic symptoms and depressive symptoms.
Reeve et al., 2018b	Mediation analysis, longitudinal, observational	Outpatients with early non-affective psychosis diagnoses.	29	Gender (male = 13), Age (m = 23.55, SD = 3.8).	Sleep-50	SPEQ	Insomnia is a significant predictor of paranoia and hallucinations both within and across time, with the relationships mediated by negative affect.
Subramaniam et al., 2018	Cross-sectional	First-episode psychosis.	279	Gender (male = 142), Age (m = 25.8, SD = 6.2).	ISI,	SCID, PANSS	Insomnia was associated with significant decreases in all QOL domains assessed in the study even after adjusting for confounders.
Hou et al., 2017	Cross-sectional	Patients with schizophrenia	623	Gender (male = 341), Age (m = 47.7, SD = 10.3).	Interview - DIS; DMS; EMA, TST	BPRS	Long sleep was associated with unemployment and use of second-generation antipsychotics.
Kilicaslan et al., 2017	Cross-sectional	Outpatients with schizophrenia	199	Gender (male = 136), Age (m = 40.42, SD = 11.20).	PSQI	SCID, PANSS	Positive association found between subjective sleep quality and positive symptoms.
Li et al., 2017	Cross-sectional	Outpatients with schizophrenia	612	Gender (male = 337), Age (m = 47.7, SD = 10.3).	Interview - DIS; DMS; EMA	BPRS	Insomnia associated with significantly lower quality of life.
Li et al., 2016	Longitudinal, observational	Outpatients with schizophrenia-spectrum diagnoses.	388	Gender (male = 175), Age (m = 41.0, SD = 11.4).	Parasomnia questionnaire	ICD-10 Diagnosis	Insomnia associated with increased incidence of suicidal behaviour.
Noort et al., 2016	Cross-sectional	Outpatients with Schizophrenia (SP, n = 30), outpatients with depression (DP, n = 30) and healthy controls (HC, n = 30).	90	Gender (male = 23), Age (m = 41.20, SD = 10.78).	PSQI	ICD-10 Diagnosis	There was a significant negative relationship between PSQI score and reading span task scores. No differences found between SP and HC on working memory tasks.
Afonso et al., 2014	Cross-sectional	Outpatients with schizophrenia (SP)	68	SP (n=34) Gender (male = 22), Age (m = 33.8, SD = 8.6). HC (n=34) Gender (male = 19), Age (m = 34.7, SD = 8.3).	Actigraphy, PSQI.	PANSS	Greater sleep disturbance, poor sleep quality and poor quality of life found in patients compared to controls.
Si et al., 2019	Cross-sectional (*"Longitudinal analyses do not include sleep item)*	Acute inpatients with schizophrenia	602	Gender (male = 289), age (m= 32.4, SD=11.31).	Sleep quality (specific measure or item not detailed).	PANSS	Sleep quality was associated with social functioning.
Langsrud et al., 2016		Acute inpatients (n=49 with schizophrenia, n=28 mood disorders, n=27 substance use, n=20 anxiety, personality or developmental disorders, n=11 organic disorder).	135	Gender (male = 74), age (m= 39.0, SD=15.6).	Sleep diary completed by nursing staff.	Diagnostic category used only. Duration of inpatient admission.	Sleep duration on the night of admission negatively correlated with length of admission.
Chiu et al., 2015	Cross-sectional	55 psychiatric inpatients with psychosis and 66 healthy controls. 25 in each group had insomnia.	121	Inpatients Gender (male = 74.5%), age (19-70) Controls (n=66, Gender (male = 42.4%), age (18-84)	ISI, Thought Control Questionnaire for Insomnia-Revised, Dysfunctional Beliefs and Attitudes about Sleep scale, Sleep Hygiene Knowledge scale, and Beliefs about Causes of Sleep Problems questionnaires	Diagnostic category used only.	Inpatients frequently reported the causes of insomnia to be related to their illness (rather than to their lifestyle factors) and had an incomplete understanding of good sleep habits.

Table 2 key: BPRS= Brief Psychiatric Rating Scale; CAARMS = Comprehensive Assessment of At-Risk Mental States; CAPE-42 = Community Assessment of Psychotic Experience; CSM = The Composite Scale of Morningness; DIS = difficulty initiating sleep; DMS = difficulty maintaining sleep; EMA = early morning wakening; EPQ = Economic Patient Questionnaire interview; ESS = Epworth Sleepiness Scale; G-PTS = Green et al. paranoid thoughts scale; ICSD-3 = International Classification of

nightmares are lacking. However, negative affect and related processes such as worry are candidate variables given their strong associations with nightmare occurrence and severity (Rek et al., 2017).

3.3.1.2. Clinical studies. In patients at ultra-high-risk of psychosis, sleep disruption has been associated with positive and negative symptoms (Lunsford-Avery et al., 2015; Poe et al., 2017), disrupted cognitive functioning (Lunsford-Avery et al., 2017), severity of psychotic experiences such as hallucinations and delusions (Reeve et al., 2019a), and overall functioning (Poe et al., 2017). In a large sample of 740 ultra-high-risk patients, sleep disruption was positively correlated with attenuated psychotic experiences, especially suspiciousness (Goines et al., 2019). Depression mediated the association between sleep problems and paranoia.

In patients with psychosis, sleep disturbance is associated with poor clinical outcomes (Afonso et al., 2014; Chung et al., 2018; Hou et al., 2017; Kilicaslan et al., 2017; Li et al., 2017). For example, a naturalistic longitudinal study of 388 patients found that insomnia was associated with an increased risk of suicide attempts (Li et al., 2016). In the only study specifically reporting correlational data in a first-episode sample, insomnia was associated with poorer outcomes on all four quality of life domains assessed (Subramaniam et al., 2018).

Only two studies with patients with psychosis reported mediation analyses (Kasanova et al., 2019; Reeve et al., 2018b). In a longitudinal observational study of 29 patients with non-affective psychosis, insomnia predicted the persistence of psychotic experiences over time: a bidirectional relationship was indicated between insomnia and paranoia however insomnia was found to be a stronger predictor of later hallucinations than the reverse direction (Reeve et al., 2018b). Mediation models were tested and found that negative affect (anxiety and depression) mediated the relationship between insomnia and psychotic experiences. This is consistent with the findings of an ESM study, in which a time-lagged mixed multilevel model was applied to distinguish the contribution of poor sleep quality on morning paranoia, and evening paranoid ideation on subsequent sleep quality (Kasanova et al., 2019). Poor sleep quality predicted elevated paranoia, and this was fully mediated by negative affect. However, no significant association was found between evening paranoia and poor sleep quality.

3.3.2. Causal tests

When the amount of sleep is deliberately reduced in experimental manipulation studies, either via total sleep deprivation (Meyhöfer et al., 2017; Petrovsky et al., 2014) or sleep restriction (Reeve et al., 2018a), it results in increases in psychotic experiences. These studies have only been conducted with non-clinical samples, but all three report sleep loss resulting in increased perceptual distortions such as hallucinations. Reeve et al., 2018a also found an increase in paranoia and cognitive disorganisation, but no significant changes in grandiosity. Mediation analyses revealed that changes in psychotic experiences were mediated by changes in negative affect and related processes (including worry and negative self and other cognitions), but not memory impairment. Together these manipulation studies provide strong evidence that sleep disturbance is a contributory cause to paranoia and hallucinatory experiences.

3.4. Interventionist-casual tests

> *"It sorted out my sleep and I'm a better person for it."* (patient 10, Waite et al., 2016a, p.187)

In the last five years, there have been six intervention studies targeting insomnia and one targeting nightmares (Table 3). These studies have typically been designed to not only test whether sleep can be improved but to find out whether psychotic symptoms reduce (an interventionist-causal approach, Kendler and Campbell, 2009). Most studies have focused on patients with persistent psychotic symptoms ($n = 3$ insomnia, $n = 1$ nightmares). There has been one study conducted in an acute inpatient setting and one with young people at ultra-high-risk of psychosis. However, the most robust finding is provided from a large RCT of university students with insomnia ($n = 3755$) (OASIS trial; Freeman et al., 2017).

The goal of the OASIS trial was to definitively test whether there is a causal association between insomnia and paranoia and hallucinations (Freeman et al., 2017). Students with self-reported insomnia were randomised to receive either a digital CBTi intervention in addition to usual care or usual care alone. Post-treatment, there were large effect size reductions in insomnia (SCI cohen's d = 1.1) and small effect size improvements in paranoia (GPTS-B d = 0.19) and hallucinations (SPEQ-H d = 0.24) in the CBTi group compared with usual care. Those who received the digital sleep treatment were less likely to meet ultra-high-risk criteria (indicated by a score ≥ 6 on the 16-item prodromal questionnaire) post treatment. Parallel analyses in the opposite direction indicated that changes in psychotic experiences explained a much smaller (approx. 3%) proportion of change in sleep. This study provides the most definitive evidence to date that sleep treatment can improve psychotic experiences and that insomnia is a contributory causal factor in paranoia and hallucinations. A key limitation is that the study was not in a clinical population.

In young people at ultra-high-risk, an uncontrolled feasibility case series (SleepWell) with 12 participants (14–24 years) found large effect size improvements in sleep (ISI d = 6.8) following an 8-session individual intervention (Bradley et al., 2018). The treatment included adaptations to account for the developmental age of participants (for example, including parents, incorporating technology) and the associated circadian phase shifts that occur during adolescence (for example, adjusting expectations of sleep timing). Compared to baseline, the confidence intervals indicated improvements in paranoia (GPTS d = 0.6), hallucinatory experiences (SPEQ-H d = 0.3), and negative affect (DASS-21 depression d = 0.5) post-treatment, yet, as appropriate for pilot studies, the *p*-values were not reported (for further statistical rationale see Lancaster et al., 2004). However, the quality of the evidence is limited by the small sample size and lack of control group.

Three studies have evaluated CBTi interventions with patients with persistent psychotic symptoms (two in outpatient settings and one in a residential setting). The Better Sleep Trial (BeST; Freeman et al., 2015) was an assessor-blind pilot randomised controlled trial with 50 patients with current psychotic symptoms. The manualised intervention was delivered on an individual basis over eight sessions. Post-treatment there were large effect size improvements in sleep: 41% of patients in the intervention group no longer had clinical insomnia (compared to 4% in the control group). However, the treatment effect estimation for delusions (PSYRATS d = 0.1 CI −2.0 to 2.6) and hallucinations (PSYRATS d = 0.2, CI −65 to 2.7) included reducing or increasing psychotic experiences. The study was underpowered to determine with any precision the effect on psychotic experiences (which led to the much larger OASIS trial). In addition to the clinical benefits, a health economic evaluation indicated that the sleep intervention may also be cost-effective (Tsiachristas et al., 2018).

In an open label trial of adapted CBTi added to usual care, compared to usual care alone, differential treatment outcomes were observed between different sleep presentations (Chiu et al., 2018). Latent class analysis was conducted on the 74 participants to identify three sleep subtypes: classic severe insomnia (44.6%), insomnia with normal sleep duration (37.8%), insomnia with hypersomnia (17.6%). The greatest treatment benefits were observed in the first cluster. In the hypersomnia cluster, total sleep time reduced and sleep onset latency was halved. A blunted treatment response was reported in the normal sleep duration cluster. However, there were comparable improvements in daytime functioning and overall psychopathology.

Within a residential rehabilitation setting, a four-session CBTi group intervention was evaluated in addition to usual care compared to usual

Table 3
Treatment evaluation studies.

Reference	Design	Sample	Intervention	Outcome		
				Treatment uptake	Sleep measures	Mental health measures
Freeman et al., 2017	Single blind randomised controlled trial of digital CBTi+TAU vs TAU alone.	3755 university students (aged 18 or over) with insomnia (≤16 SCI) from 26 universities across the UK. 1043 (28%) male, 2676 (71%) female, 36 (1%) other. Mean age 24.7 years. 1891 treatment, 1864 control. There were no exclusion criteria.	6 sessions. Digital CBTi programme: Sleepio. The interactive programme is available on an online platform. Completion of an initial assessment drives algorithms which personalise the intervention. Treatment techniques include behavioural (eg sleep restriction), cognitive (eg paradoxical intention) and educational (eg sleep hygiene, sleep processes) components.	1302 (69%) completed at least 1 session; 672 (36%) completed 3 sessions; 331 (18%) completed all 6 sessions. Mean sessions Treatment quality/fidelity standardised due to digitised delivery method.	Significant reductions in sleep disturbance at all timepoints. Post treatment (10 weeks) there were large effect size improvements on the SCI (Cohen's d = 1.11). Change in sleep at 3 weeks explained 30% of the intervention effect on paranoia at 10 weeks; change in sleep at 10 weeks accounted for 58% of the treatment effect on paranoia. Change in sleep at 3 weeks explained 21% of the intervention effect on hallucinations post-treatment; change in sleep at 10 weeks accounted for 39% of the intervention effect on hallucinations.	Significant reductions in paranoia and hallucinations at all timepoints. Small effect size changes post treatment for paranoia GPTS-B (d = 0.19) and hallucinations SPEQ-H (d = 0.24). Improvements in depression (PHQ-9), anxiety (GAD-7), prodromal symptoms (Prodromal questionnaire), nightmares (DDNSI), psychological wellbeing (WEMWBS) and functioning (WSAS) were reported. There was a small increase in mania symptoms (Altman-Mania) in the treatment group.
Bradley et al., 2018	Uncontrolled, feasibility case series of adapted CBTi+TAU.	12 young patients (aged 14–24 years) at ultra-high-risk of psychosis (CAARMS attenuated psychosis criteria) with current sleep problems (≥15 ISI or above cut off on the insomnia or CRD subscales of the SLEEP-50). 6 male, 5 female. Mean age 18.9 years (SD = 1.9). No control group.	8 sessions (10 week treatment window). Individual. Treatment techniques targeted both insomnia (eg stimulus control, sleep hygiene, relaxation) and circadian rhythm disruption (eg sleep/wake realignment, daily activity). Treatment adaptations to account for developmental age and sleep architecture during adolescence are outlined.	11 (92%) completed ≥2 sessions. Mean number of sessions 7.36(SD 0.5). Treatment quality and fidelity not reported.	Large effect size improvement in sleep post treatment (12 weeks) and at follow up (16 weeks) on all measures of sleep: ISI (Cohen's d = 6.8); Sleep-50 (d = 1.7); PSQI (d = 2.9).	Small and medium effect size improvement post treatment in paranoia (d = 0.6, GPTS), hallucinations (d = 0.3, SPEQ), depression (d = 0.5, DASS-21), stress (d = 0.8, DASS-21) and anxiety (d = 0.2 DASS-21).
Freeman et al., 2015	Prospective, assessor blind pilot RCT of CBTi+ TAU vs TAU alone.	50 patients with persistent distressing delusions and/or hallucinations (≥2 PSYRATS) in the context of a diagnosis of non-affective psychosis and insomnia (≥15 ISI). 34 (68%) male 16 (32%) female. Mean age 40.9 years. 24 treatment, 26 control.	8 sessions (12 week treatment window). Individual. Treatment techniques included: Psychoeducation, assessment and goal setting, stimulus control, establishing daytime routine and circadian rhythm, sleep hygiene, relaxation, cognitive therapy to address sleep-related beliefs. Treatment manual outlines key techniques and adaptations – see Waite et al. (2016b).	23 (96%) completed >4 sessions. Mean number of sessions 7.3 (SD 1.9). Treatment quality and fidelity assessed.	Large effect size improvement in sleep post treatment (Cohen's d = 1.9 at 12 weeks) and maintained at follow up (d = 1.2 at 24 weeks) as measured on the primary measure the ISI. Consistent findings on other sleep measures including the PSQI.	Small effect size improvements (d = 0.1 to −0.3) in delusions and hallucinations were reported (PSYRATS, GPTS, PANSS). However, the confidence intervals span 0. Therefore, treatment effect estimations range from reducing to increasing delusions and hallucinations. Small to medium effect size improvements in fatigue (MFI), wellbeing (WEMWBS, CHOICE), and quality of life (EQ5D) were reported.
Chiu et al., 2018	Open label trial of CBTi+TAU vs TAU alone.	74 patients with non-affective psychosis attending outpatient clinics, with insomnia symptoms (≥5 PSQI). 39 (53%) male, 35 (47%) female. Mean age 41.4 years. 50 treatment, 24 control. Latent class analysis used to identify	4 sessions (6 week treatment window). Individual. Session outline: Treatment manual outlines key techniques and adaptations – see Waters et al., 2017.	40 (80%) completed ≥2 sessions. Mean number of sessions not reported. Treatment quality and fidelity not reported.	Significant improvements in sleep (PSQI; sleep hygiene behaviours scale; TST; SE; SOL) at 6 weeks (post-treatment). Differences observed by profile: Cluster 1 – Greatest benefits: longer TST and SE. Cluster 2 – blunted treatment	Significant improvements in severity of psychotic symptoms (MINI) and psychological distress (PHQ-4) post -treatment.

		three sleep subtypes. Cluster 1 – Classic severe insomnia (44.6%) Cluster 2 – Insomnia with normal sleep duration (37.8%) Cluster 3– Insomnia with hypersomnia (17.6%)			response compared to cluster 1; improvements in daytime functioning. Cluster 3 – reduced TST, reduced SOL.	
Hwang et al., 2019	Non-randomised, assessor blind, evaluation of group CBTi+TAU vs TAU alone.	63 patients of a residential facility with a diagnosis of non-affective psychosis, current (but stable) psychotic symptoms (PSYRATS), and current insomnia (≥15 ISI). 41 (65%) male, 22 (35%) female. Mean age 44.9 years. 31 treatment, 32 control.	4 sessions. Group format (group size 2–9 participants). Treatment components: Psychoeducation, cognitive therapy, sleep hygiene, stimulus control, sleep restriction, sleep diary completion.	Treatment uptake not reported. However, all participants provided outcome and follow-up data. Mean number of sessions not reported. Treatment quality and fidelity not reported.	Significant reductions in sleep dysfunction as measured on the ISI and PSQI at 4 weeks (post-treatment) and 8 weeks (follow up).	No significant change in psychotic symptoms (PSYRATS), nor depression the BDI, or anxiety measured on the anxiety sensitivity index (ASI).
Sheaves et al., 2018a	Assessor blind pilot RCT of sleep treatment (STAC) + TAU vs TAU alone.	40 inpatients on an acute psychiatric ward with self-reported symptoms of insomnia (≥8 ISI). 18 (45%) diagnosis of non-affective psychosis. 40 (100%) male. Mean age 40 years 20 treatment, 20 control.	2-week treatment window. Number of sessions was flexible. Minimum dose defined as 5 sessions. Individual. Sleep treatment at acute crisis (STAC) includes CBTi, sleep monitoring, and light/dark exposure for circadian entrainment. Treatment manual outlines key techniques and adaptations – see Sheaves et al. 2018.	20 (100%) completed treatment. Mean number of sessions 4.8 (SD 0.6). Treatment quality and fidelity not reported.	Large effect size reductions in insomnia (ISI) at post treatment (2 weeks) (d = 0.9) maintained at follow up (12 weeks).	Small improvements in psychological wellbeing (WEMWBS) post treatment (2 weeks) (d = 0.3). Wide confidence intervals for STAC increasing or decreasing psychiatric symptoms (PANSS, BSS, YMRS) Patients in the treatment group were discharged 8.5 days earlier.
Sheaves et al., 2019	Assessor blind parallel group pilot RCT of brief CBT for nightmares (including IRT) + TAU vs TAU alone.	24 patients with weekly nightmares and persecutory delusions in the context of a diagnosis of non-affective psychosis. 14 (58%) male 10 (42%) female. Mean age 41 years. 12 treatment, 12 control.	4 week treatment window. Individual. Core technique was imagery rehearsal training. Additional strategies included: psychoeducation about nightmares, reducing pre-sleep hyperarousal, increasing coping skills, reducing preoccupation with nightmares, stabilising REM sleep.	12 (100%) completed treatment. Mean number of sessions 8.6 (SD 1.5). Treatment quality and fidelity not reported.	Large effect size reductions in nightmares (DDNSI) and insomnia (SCI) at post treatment (4 weeks) (DDNSI d = −1.06; SCI d = −1.4) maintained at follow up (8 weeks).	Post-treatment improvements were observed in paranoia (GPTS), affective symptoms (DASS-21), dissociation (DES-B), and emotional wellbeing (WEMWBS). There were no changes in hallucinations (CAPS) or activity levels (time budget).

Table 3 key: BDI = Beck depression inventory; BSS = Beck suicide scale; CAARMS = Comprehensive assessment of at-risk mental states; CAPS = Cardiff anomalous perceptions scale; CHOICE = Choice of outcome in CBT for psychoses; CRD = Circadian rhythm disruption; DASS-21 = Depression, anxiety and stress scale; DES = Dissociative experiences scale; DDNSI = Disturbing dream and nightmare severity index; GAD-7 = Generalised anxiety disorder assessment; GPTS = Green et al. paranoid thoughts scale; MFI = Multidimensional fatigue inventory; PANSS = Positive and negative syndrome scale; PHQ-9 = Patient health questionnaire; PSQI = Pittsburgh sleep quality index; PSYRATS = Psychotic symptom rating scales; RCT = Randomised controlled trial; SCI = Sleep condition indicator; SE = Sleep Efficiency; SOL = Sleep Onset Latency; SPEQ = Specific psychotic experiences questionnaire; STAC = Sleep treatment at acute crisis; TAU = Treatment as usual; TST = Total sleep time; WEMWBS = Warwick-Edinburgh mental wellbeing scale; WSAS = Work and social adjustment scale; YMRS = Young mania rating scale.

care alone (Hwang et al., 2019). This was a non-randomised, assessor blind trial with 63 patients. No significant changes in psychotic symptoms, depression or anxiety were found, although the study was underpowered. Significant improvements in sleep were reported post-treatment (4 weeks) and at follow-up (8 weeks). However, the effect sizes (ISI d = 0.8 at 8 weeks) were smaller than those reported in the BeST trial (ISI d = 1.9 at 12 weeks). This may indicate that longer treatment duration or individual rather than a group format is important for achieving large treatment effects.

In acute settings, an assessor-blind pilot RCT of a novel sleep intervention has been conducted (Sheaves et al., 2018a). Eighteen (45%) of the 40 participants, recruited from a single ward, had a diagnosis of non-affective psychosis. The intervention included CBTi, sleep monitoring, and light/dark exposure for circadian entrainment. In this acute setting the entire intervention was delivered in 2 weeks. Compared to usual care, there were large effect size reductions in insomnia (ISI d = 0.9) at post-treatment and follow-up (12 weeks). This was the only intervention study to report the outcome on negative symptoms: there was an indication of a small effect size improvement (d = 0.3), however the confidence intervals were wide, including zero, and so the findings are not conclusive. Patients who received the sleep intervention were discharged on average 8.5 days earlier.

One pilot RCT has evaluated imagery rehearsal training (IRT) to reduce nightmare severity in 24 patients with persecutory delusions (Sheaves et al., 2019). In addition to IRT, the intervention included CBT techniques to target identified causal factors for nightmares, for example reducing worry and oversleeping. Large effect size improvements in nightmare severity (DDNSI d = 1.1) and insomnia (SCI d = 1.4) were reported post-treatment (4-weeks) and maintained at follow-up (8-weeks). There was a medium effect size treatment benefit on paranoia favouring the CBT group at both 4 and 8 weeks. However, the confidence intervals are wide, hence a larger trial is required to estimate the effect with greater precision. There was no effect of the treatment on hallucinations which fits with the understanding that psychotic experiences are distinct phenomena with different causal factors (Peralta and Cuesta, 1999; Zavos et al., 2014).

4. Discussion

There has been a sharp rise in the number of studies investigating sleep disruption and psychosis: the number of quantitative investigations has doubled in the last five years. There are numerous correlational studies, both in clinical and correlational studies, both in clinical and non-clinical studies, often substantial, that robustly support the co-occurrence of subjective sleep disruption and certain psychotic experiences across the spectrum of psychosis severity. Yet the mechanisms underpinning this relationship remain uncertain. Patient accounts consistently highlight the importance and negative impact of sleep problems and a desire for treatment. The principal advance has been the evaluation of adapted CBT for sleep disorders in patients with non-affective psychosis. The trials have generally been small, limiting the ability to determine the effect of improving sleep on psychotic experiences. Yet taken together an initial clinical picture forms: sleep disturbance is a common and treatable problem across the spectrum of psychosis severity that leads to small improvements in psychotic symptoms such as paranoia and hallucinations. To date, the OASIS trial (Freeman et al., 2017) provides the strongest test, showing that improving insomnia leads to improvements in paranoia and hallucinations. However, studies have been inadequately powered to test this in clinical populations.

There may be differences between how individual psychotic experiences are linked to distinct sleep disorders. In a study of 5000 adolescent twin pairs, the genetic and environmental influences of sleep disturbance were found to overlap with those for paranoia, hallucinations, and cognitive disorganisation but not grandiosity and anhedonia (Taylor et al., 2015). In a robust experimental test of sleep restriction, negative affect was found to mediate the relationship between sleep loss and paranoia but not hallucinations (Reeve et al., 2018a). There are many plausible mechanisms, both psychological and biological, one might expect to underpin the association between sleep dysfunction and psychotic experiences. The most consistent evidence, at a psychological level, is for the role of negative affect mediating the association between insomnia and psychotic experiences (principally paranoia) (Freeman et al., 2009, 2017; Kasanova et al., 2019; Reeve et al., 2015; Reeve et al., 2018a). Other potential routes include alexithymia, and dissociation, which could be further linked to adversity or trauma. Further work is needed to understand the mechanisms linking hallucinations and insomnia. Studies investigating the interaction of sleep problems with grandiosity, cognitive distortion, or negative symptoms are rare. This review has focused on psychological models, as this is the framework underpinning the first-line recommended treatment (CBTi), yet neurodevelopmental and neurochemical mechanisms are also plausible (Lunsford-Avery and Mittal, 2013). For example, abnormalities in the interacting neurotransmitter systems and neural circuits observed in sleep and circadian disruption are also implicated in the aetiology of psychosis (Wulff et al., 2010). At the neurobiological level, overactivity of dopamine receptors are implicated in both the causation of positive psychotic symptoms and wakefulness (Monti and Monti, 2005). To date, we do not have clear evidence to indicate the primary route.

Understanding the mechanistic links will help in the adaptation and improvement of treatment, however it could be argued the key line of research needed now is how to provide the best evidence-based treatments for patients. Psychological interventions for sleep disturbance are applicable, feasible, and demonstrate large effect size improvements in insomnia and nightmares in patients with psychosis. This is consistent with the evidence-base for these treatments in other mental health disorders. The treatment is popular with patients with psychosis: the uptake rate is strikingly high (80–100%) and qualitative data indicate that patients value the opportunity to address sleep disturbance. The studies reporting the largest effect sizes made adaptations to standard treatment protocols. One key adaptation is the use of sleep restriction *principles*, without applying the formal sleep restriction protocol. In practice, this involves a degree of flexibility, sharing the aims of the procedure to reduce time in bed not sleeping and careful negotiation to set a 'sleep window'. This is particularly important given the experimental evidence for the impact of sleep restriction in the occurrence of psychotic experiences (Reeve et al., 2018a). Screening and evaluation of treatment progress can be achieved using brief self-report measures (for example, Insomnia Severity Index (Morin et al., 2011)) yet they are infrequently used in current practice (Rehman et al., 2017). Treatment protocols outlining adaptions for patients with psychosis have been produced (for example, Sheaves et al., 2018b; Waite et al., 2016b; Waite and Sheaves, 2020; Waters et al., 2017). The next challenge is implementation.

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Declaration of competing interest

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Chapter 2 - Appendices

2.1 Published manuscript: Waite, F., Černis, E., Kabir, T., Iredale, E., Johns, L., Maughan, D., Diamond, R., Seddon, R., Williams, N., Yu, L.-M., & Freeman, D. (2023). A targeted psychological treatment for sleep problems in young people at ultra-high risk of psychosis in England (SleepWell): A parallel group, single-blind, randomised controlled feasibility trial. *The Lancet Psychiatry*, *10*(9), 706–718. https://doi.org/10.1016/S2215-0366(23)00203-1

A targeted psychological treatment for sleep problems in young people at ultra-high risk of psychosis in England (SleepWell): a parallel group, single-blind, randomised controlled feasibility trial

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Summary

Background Sleep disturbance is common and problematic for young people at ultra-high risk of psychosis. Sleep disruption is a contributory causal factor in the occurrence of mental health problems, including psychotic experiences, anxiety, and depression. The implication is that treating sleep problems might have additional benefits on mental health outcomes in individuals at high risk. The present study had two aims: first, to establish the feasibility and acceptability of a randomised controlled trial to treat sleep problems with the aim of reducing psychotic experiences in young people at ultra-high risk of psychosis; and second, to provide proof of concept of the clinical efficacy of the treatment.

Methods We did a parallel group, single-blind, randomised controlled feasibility trial in two National Health Service trusts in England. Eligible participants were aged 14–25 years, a patient of mental health services, assessed as being at ultra-high risk of psychosis on the Comprehensive Assessment of At-Risk Mental States, and having current sleep problems (score of ≥15 on the self-report Insomnia Severity Index [ISI]). Participants were randomly assigned (1:1) to either a targeted psychological therapy for sleep problems (SleepWell) plus usual care or usual care alone via an automated online system, with non-deterministic minimisation that balanced participants for ISI score and referring service. The SleepWell therapy was delivered on an individual basis in approximately eight 1-h sessions over 12 weeks. Assessments were done at 0, 3, and 9 months, with trial assessors masked to treatment allocation. The key feasibility outcomes were the numbers of patients identified, recruited, and retained, treatment uptake, and data completion. Treatment acceptability was measured with the Abbreviated Acceptability Rating Profile (AARP). In preliminary clinical assessments, the primary clinical outcome was insomnia at 3 and 9 months assessed with the ISI, reported by randomised group (intention-to-treat analysis). Safety was assessed in all randomly assigned participants. The trial was prospectively registered on ISRCTN, 85601537, and is completed.

Findings From Nov 18, 2020, to Jan 26, 2022, 67 young people were screened, of whom 40 (60%) at ultra-high risk of psychosis were recruited. Mean age was 16·9 years (SD 2·5; range 14–23), and most participants identified as female (n=19 [48%]) or male (n=19 [48%]) and as White (n=32 [80%]). 21 participants were randomly assigned to SleepWell therapy plus usual care and 19 to usual care alone. All participants provided data on at least one follow-up visit. 39 (98%) of 40 participants completed the primary outcome assessment at 3 and 9 months. 20 (95%) of 21 participants assigned to SleepWell therapy received the prespecified minimum treatment dose of at least four sessions. The median treatment acceptability score on the AARP was 48 (IQR 46 to 48; n=17; maximum possible score 48). At the post-intervention follow-up (3 months), compared with the usual care alone group, the SleepWell therapy group had a reduction in insomnia severity (ISI adjusted mean difference −8·12 [95% CI −11·60 to −4·63]; Cohen's d=−2·67 [95% CI −3·81 to −1·52]), which was sustained at 9 months (ISI adjusted mean difference −5·83 [−9·31 to −2·35]; Cohen's d=−1·91 [−3·06 to −0·77]). Among the 40 participants, eight adverse events were reported in six participants (two [11%] participants in the usual care group and four [19%] participants in the SleepWell therapy group). One serious adverse event involving hospital admission for a physical health problem was reported in the SleepWell therapy group, and one patient in the usual care alone group transitioned to psychosis. None of these events were classed as being related to trial treatment or procedures.

Interpretation A randomised controlled trial of a targeted psychological sleep therapy for young people at ultra-high risk of psychosis is feasible. Patients can be retained in the trial and assessments done by masked assessors. Uptake of the sleep therapy was high, and we found preliminary evidence of sustained reductions in sleep problems. A definitive multicentre trial is now needed.

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Introduction

The presence of attenuated psychotic symptoms and disruption to everyday life are key criteria used to identify young people (aged 14–25 years) at ultra-high risk of psychosis. This group of young people are also at increased risk of other mental health problems, such as depression, and often experience poor long-term outcomes. Although these young people often seek help, current treatment effects are limited.[1,2] New approaches are needed. Our focus is on identifying and targeting causal mechanisms that are developmentally important, and problematic in their own right, and that young people want treated, such as sleep disruption.

Sleep problems are widespread in young people at ultra-high risk of psychosis, with estimates of prevalence exceeding 75%.[3] Sleep problems in early psychosis are not only common but also complex.[4] The rates of comorbidity are high between different sleep disorder presentations, including insomnia, nightmares, circadian rhythm disruption, and hypersomnia.[4] In qualitative accounts, young people at ultra-high risk of psychosis describe a range of sleep problems, including disrupted sleep timing and an irregular sleep schedule, difficulties getting to sleep and sustaining sleep, and distressing nocturnal experiences such as night-time worry, hallucinatory experiences, and nightmares.[5] The daytime effects include poor attendance and engagement at school or work, difficulties sustaining friendships and interacting in social situations, and a decline in mental health.[5]

Longitudinal,[6] experimental,[7] and interventionist[8,9] studies have identified sleep disturbance as a putative contributory causal factor in the occurrence of psychotic experiences, including paranoia and hallucinations.[10,11] In young people at ultra-high risk of psychosis, sleep problems might also be predictive of transition to psychosis.[12] Therefore, treating sleep problems might lead to improvements in wider mental health outcomes. However, to successfully tackle sleep disturbance in this group, treatment needs to address the complexity of sleep presentations, via techniques to improve sleep pressure, align circadian timing, and reduce hyperarousal.

The gold standard treatment for insomnia, cognitive behavioural therapy (CBT),[13] has been successfully adapted for people with psychosis.[9,14,15] Across the spectrum of severity of psychosis, our team have

Research in context

Evidence before this study

Chronic sleep disruption is common in patients with mental health conditions, and is a contributory causal factor in the occurrence of mental health disorders. It can be successfully treated by cognitive behavioural approaches, which might lead to reductions in anxiety, depression, and psychotic experiences. This relationship has relevance in young patients at ultra-high risk of psychosis, who are especially vulnerable to a range of poor mental health outcomes. On Dec 21, 2022, we searched PubMed without date or language restrictions using the following search terms: ("sleep"[All Fields] OR "insomnia"[All Fields] OR "circadian rhythm disruption"[All Fields]) AND ("clinical high risk"[All Fields] OR "ultra high risk"[All Fields] OR "at risk mental state"[All Fields] OR "prodromal"[All Fields]) AND ("treatment"[All Fields] OR "intervention"[All Fields]). 50 papers were identified. We found no randomised controlled trial that had evaluated the treatment of sleep disruption in young patients at ultra-high risk of psychosis. We identified six potentially informative studies. Four longitudinal studies found that sleep disturbance in patients at ultra-high risk of psychosis predicted the persistence of psychotic experiences over time. Another study, reported by our team, described the results of a case series in which a targeted sleep treatment was tested in 12 young people at high risk of psychosis, which provided an initial indication of feasibility and potential benefit. An accompanying qualitative study detailed that the treatment of sleep problems was highly valued by patients and that it had a meaningful effect on psychological wellbeing.

Added value of this study

To our knowledge, this is the first randomised controlled trial of a targeted psychological intervention (SleepWell) to treat sleep problems in young people at ultra-high risk of psychosis. All feasibility markers were achieved. Patients were successfully recruited, treatment uptake and follow-up rates were high, and all assessments were completed by assessors masked to group allocation. Acceptability of the SleepWell intervention was also high. Preliminary clinical outcomes indicated improvements in sleep after the intervention (3 months), which were sustained at follow-up (9 months). We also found indications of potential benefits on other mental health symptoms, including anxiety, depression, and paranoia. The present clinical data provide proof of concept for the potential benefits of treating sleep in young people at ultra-high risk of psychosis.

Implications of all the available evidence

A randomised controlled clinical trial testing the addition of psychological sleep therapy to standard care is feasible. Consistent with trials in patients with diagnosed psychosis, our findings suggest that psychological therapy can improve sleep in young people at ultra-high risk of psychosis. The intervention might also have benefits on wider mental health outcomes, including psychotic experiences. A definitive multicentre trial to establish the full range of effects of cognitive behaviour therapy for sleep disturbance, particularly on psychotic experiences, is warranted.

consistently demonstrated large treatment effects on sleep problems (effect size range d=0·9–1·9).[3,14,15] Potential further benefits have been indicated for depression, anxiety, and psychotic experiences.[3] Treatment effects on psychotic experiences might be mediated by affective symptoms.[4–6]

The common, non-specific occurrence of sleep problems across mental health problems[11] might hold particular meaning when considered from a network perspective, in which the presentations of mental health problems are understood to reflect dynamic networks of interacting symptoms.[16] The implication is that targeting these common factors might lead to a reduction in the specific treatment target and also to benefits across the network of symptoms. This position is consistent with the clinical staging approach, in which sleep disturbance is identified as a potential early treatment to reduce the likelihood of a range of severe mental health problems.[17]

See Online for appendix 1

We adapted our CBT for insomnia treatment specifically for young people at ultra-high risk of psychosis. In an uncontrolled case series with 12 young patients (aged 15–22 years), we found large improvements in sleep, with smaller benefits on depression and psychotic experiences.[18] The treatment was popular (for example, 74 [88%] of 84 sessions attended) and in qualitative accounts, the young patients described the importance and value of gaining both knowledge ("learnt a lot") and skills ("developed a repertoire of skills") to improve sleep.[5]

In this Article, we report on a randomised controlled trial that aimed to assess the feasibility, acceptability, and preliminary clinical efficacy of a targeted intervention to improve sleep (SleepWell) and reduce psychotic experiences in young people at ultra-high risk of psychosis. Our hypotheses related to preliminary clinical outcomes were that, compared with usual care, SleepWell therapy added to usual care would, firstly, reduce insomnia and other sleep disruption (post-treatment); secondly, reduce psychotic experiences (a key marker of psychosis risk) and rates of transition to psychosis (post-treatment); thirdly, reduce psychiatric symptoms (depression, anxiety, worry, and suicidal ideation), increase activity and social functioning, improve physical health, and enhance quality of life (post-treatment); and fourthly, treatment effects would be maintained at follow-up. As this was a feasibility trial, it was not powered to test for statistical significance with regard to these preliminary clinical outcomes.

For **Sortition** see https://www.phc.ox.ac.uk/research/resources/sortition-clinical-trial-randomisation-software

Methods

Study design

We did a prospective, parallel group, single-blind, randomised controlled feasibility trial of the SleepWell intervention with 3-month and 9-month follow-up in two National Health Service (NHS) mental health trusts in England: Oxford Health NHS Foundation Trust (Oxfordshire and Buckinghamshire, UK) and Berkshire Healthcare NHS Foundation Trust (Berkshire, UK). The study received ethical approval from the Health Research Authority and Health and Care Research Wales in the UK (Integrated Research Application System reference number 281235, The SleepWell Trial) and NHS South Central – Oxford A Research Ethics Committee (reference number 20/SC/0281). The study was done in accordance with CONSORT guidelines.[19] The trial was prospectively registered with the ISRCTN registry (ISRCTN85601537), and the protocol[20] was published at the start of the trial (and before patient recruitment; accepted for publication Oct 7, 2020) and is provided in appendix 1. A lived experience advisory group, facilitated by the McPin Foundation (London, UK), advised on the conduct of the trial throughout.

Participants

Participants were eligible if they were aged 14–25 years, a patient of mental health services at the time of referral to the study, met diagnostic criteria for ultra-high risk of psychosis on the Comprehensive Assessment of At-Risk Mental States (CAARMS),[21] were having current sleep problems (identified by a score of ≥15 on the Insomnia Severity Index [ISI][12]), wanted help to improve sleep, and were willing and able to give informed consent (or assent with parent or guardian consent for participants aged 14–15 years) for participation in the trial. Exclusion criteria were diagnosis of a primary severe mental health problem (including psychosis, bipolar disorder, and personality disorder), probable primary diagnosis of sleep apnoea, a primary diagnosis of alcohol or substance use disorder, organic syndrome, or clinically significant learning disability, or current engagement in any other individual psychological therapy. All participants provided written informed consent, or assent with parent or guardian written consent for participants aged 14–15 years, before participation.

Randomisation and masking

Participants were randomly assigned (1:1) to either SleepWell therapy in addition to usual care for patients at ultra-high risk of psychosis, or to usual care alone. Randomisation was done by the trial coordinator (EC) with use of a validated and automated online system, Sortition, designed by the University of Oxford Primary Care Clinical Trials Unit (Oxford, UK). Allocation used a non-deterministic minimisation to ensure balance across groups with respect to severity of sleep disturbance (ISI score ≤21 *vs* ≥22) and referring service (early intervention in psychosis service [EIS] *vs* child and adolescent mental health service [CAMHS] *vs* improving access to psychological therapies service [IAPT]). Trial assessors were masked to group allocation for all assessments. The trial coordinator informed all patients of the randomisation outcome, to ensure the trial assessors remained masked to group allocation. If group allocation was revealed, the assessment was completed by another

masked assessor. Assessors were unmasked on three occasions (two by 3 months and one additional assessor by 9 months) and all assessments were successfully remasked.

Procedures

The SleepWell therapy was designed to be delivered on an individual basis in approximately eight 1 h-sessions over a 12-week period. Additional contact between sessions (eg, text messages and email) was provided to support the implementation of treatment strategies. The treatment was delivered by clinical psychologists (EČ, RD, and FW). Weekly clinical supervision of treatment was provided by FW. The treatment sessions were done at the patient's home, at an NHS clinic at the study sites, or adapted in consideration of COVID-19 restrictions for remote delivery. Flexibility in the location, duration, and number of sessions was provided to maximise engagement and uptake with this clinical group.

The SleepWell therapy is a psychological intervention designed for young people (14–25 years) and targets three mechanisms that regulate sleep: sleep pressure, circadian rhythm, and hyperarousal.[23] To address sleep pressure (the need or propensity for sleep), we promote daytime activity to increase night-time tiredness. We use the motivational benefits of fitness-trackers and focus on morning routines to also assist with circadian alignment. To address circadian alignment (the timing of sleep), we realign sleep patterns with the environment by using light and dark exposure, which is the key zeitgeber, or time cue, for the sleep–wake cycle. We also re-establish circadian rhythms using daily activity timepoints (ie, a specific activity at a set time), social connection, and mealtimes. To address hyperarousal, which can disrupt sleep despite high sleep pressure and circadian entrainment, the key strategy is stimulus control, in which patients relearn the association between bed and sleep. We also use worry reduction strategies, cognitive restructuring techniques, and night-time relaxation. The treatment is informed by standard CBT sleep protocols[24,25] and protocols for treating sleep disruption in patients with psychosis,[26,27] with specific adaptations for the unique aspects of sleep in young people. These include biological changes in sleep architecture during adolescence, such as delayed circadian sleep phase, and lifestyle factors such as exam pressure, social networks, and environmental constraints (eg, shared accommodation with siblings or at university).[18]

The SleepWell intervention is manualised in a modular format and covers five core modules. The format and manuals were developed in collaboration with our lived experience advisory group. The first module covers psychoeducation about sleep disruption and the key factors needed for good sleep, assessment of current sleep difficulties and maintaining factors, formulation, and goal setting. The assessment includes a checklist of factors that commonly disrupt sleep (eg, absence of a consistent sleep schedule; inactivity in the daytime; worry at night; nightmares; hearing voices at night; and environmental and lifestyle factors such as too much light in the bedroom at night or high caffeine intake).[26,27] This enables the young person to self-identify maintaining factors, which can be used to build the formulation and to identify treatment targets. Within the goal setting segment, we aim to establish an ideal sleep window, which is the ideal time the young person would like to be asleep. Achieving sleep within the ideal sleep window is often a primary focus of treatment. To achieve the treatment goals there are three core treatment modules, with four additional modules that can be selected by patients on the basis of individual need, enabling the intervention to be personalised. The first core treatment module focuses on establishing the environmental and lifestyle context for sleep; the second focuses on stimulus control and strategies to reduce hyperarousal; the third focuses on circadian entrainment (using light and dark exposure, establishing the sleep window, and boosting zeitgebers such as meal and activity times). Given the common shift in adolescence to a delayed-phase circadian pattern, additional emphasis was put on establishing a consistent sleep window and then adjusting the timing of this window to align with the young person's ideal time. For many young people there are societal constraints on this, such as school start times or working night shifts. The additional treatment modules cover night-time worry, nightmares, relaxation, and unusual experiences such as hearing voices or seeing shapes or figures. The final core module focuses on consolidating learning, setting future goals, and relapse prevention. The key adaptions for individuals at ultra-high risk of psychosis include: addressing the developmental issue of delayed-phase circadian patterns; establishing a sleep team to support the young person by engaging family, friends, and school teachers; addressing psychotic experiences that affect sleep; problem solving around constraints on stimulus control due to the sleep environment (eg, sharing a bedroom with a sibling, or the bedroom needing to be used for study or socialising); and navigating external stressors that affect sleep (eg, living independently for the first time or taking exams). Formal sleep restriction was not used due to not wanting to cause any large reduction in sleep time on any given night during treatment.

With patient consent, sessions were audiorecorded to check the quality of the therapy. Tapes were rated for fidelity and competence using the Revised Cognitive Therapy Scale.[28] All assessed tapes were scored as providing satisfactory cognitive therapy or above (ie, a score of ≥3 on each item of the Cognitive Therapy Scale).

SleepWell was provided in addition to usual care. Usual care was recorded with the Client Service Receipt Inventory (CSRI),[29] with information on psychiatric admissions and medication collected from electronic medical records. Usual care typically consisted of

infrequent contact with a general practitioner or mental health professional for assessment, and prescription of psychotropic medication (most often antidepressant medication) as needed. There were no changes to usual care as a result of participating in the trial.

See Online for appendix 2

Study assessments were conducted at 0 months (baseline, before randomisation), 3 months (post-intervention), and 9 months after randomisation. At the end of their participation in the study, participants in the usual care alone group were offered a one-off session with a clinical psychologist (EČ or FW). This session briefly identified a plan to improve sleep, which participants could then implement independently. The importance of offering this session was emphasised by the lived experience advisory group.

Demographic and clinical data were collected by self-report and screening medical records. Gender was self-reported according to the options: male, female, other, or prefer not to say. With regard to protocol amendments, COVID-19 restrictions were in place throughout the recruitment period, including two periods of national lockdown in England (starting in November, 2020, and January, 2021). Remote working practices were used when necessary, and measures such as wearing personal protective equipment were in place throughout recruitment and follow-up. Being at moderate or high risk of a severe course of COVID-19 was added as an exclusion criterion on Sept, 1, 2020. This was modified on Feb 18, 2021, so that when an individual at moderate or high risk had been fully vaccinated (two doses), they could then enter the trial. In a separate amendment, the sleepiness and fatigue scale listed in the protocol was excluded from the statistical analysis plan as it had not been published at the time of creating the analysis plan.

Outcomes

Our aims were to assess the feasibility and acceptability of a targeted sleep intervention to prevent psychosis in young people at ultra-high risk of psychosis, and to provide a preliminary indication of clinical efficacy. The key markers of feasibility were the numbers of patients identified, recruited, and retained at 3 and 9 months, treatment uptake, and data completion at 3 and 9 months. These markers were considered the most important parameters for the design of a future trial. For assessment of treatment uptake, the prespecified minimum treatment dose was defined as four SleepWell therapy sessions, consistent with previous studies.[9,18] Treatment acceptability was measured with the Abbreviated Acceptability Rating Profile (AARP; higher scores indicate greater acceptability, maximum total score 48).[19] Other feasibility and acceptability measures are listed in the protocol (appendix 1 pp 12–13). Qualitative feedback collected via interviews is not reported herein and will be reported separately.

The primary outcome for our preliminary clinical hypotheses was insomnia at 3 and 9 months, assessed with the ISI[20] (a seven-item self-report measure scored on a 5-point Likert scale [0–4] with established clinical cut-offs: absence of insomnia [0–7]; subthreshold insomnia [8–14]; moderate insomnia [15–21]; and severe insomnia [22–28]).[22] In addition, three key secondary outcomes were selected to test our preliminary hypotheses (appendix 2 pp 8–9). These outcomes were psychotic experiences, measured with the CAARMS (Global Rating Scale for symptom severity)[21] and Revised Green et al Paranoid Thoughts Scale (R-GPTS),[23] and depression and anxiety symptoms (shown to be a mediator of the relationship between sleep disturbance and psychotic experiences[5,24]) measured with the Depression Anxiety Stress Scales–21 items (DASS-21).[25] The depression and anxiety subscales of the DASS-21 were used as key outcomes as they related to the clinical hypothesis. Higher scores on each of these measures indicates greater severity.

Other secondary clinical outcomes for sleep were based on a sleep diary and a second measure focused on circadian rhythm (SLEEP-50 Circadian Rhythm Disruption subscale[26]). Participant-reported information in sleep diaries was used to calculate total sleep time per night, sleep onset latency per night, sleep efficiency, and sleep regularity. Sleep efficiency was calculated as the total time spent asleep in a night as a percentage of total amount of time spent in bed, and sleep regularity as the standard deviation of the mean sleep midpoint time across the sleep diary. Additional secondary outcomes on psychotic experiences included hallucinatory experiences (Specific Psychotic Experiences Questionnaire–Hallucinations subscale [SPEQ-H][14]) and dissociation (Černis Felt Sense of Anomaly scale[15]). Further outcomes on psychiatric symptoms included suicidal ideation (Columbia Suicide Severity Rating Scale [CSSRS][16]), worry (Dunn Worry Questionnaire[27]), and beliefs about the self (Brief Core Schema Scale[28]). Outcomes on activity and social functioning included daily activity (time budget[29]), functioning (Work and Social Adjustment Scale[30]), and agoraphobic avoidance (Oxford Agoraphobic Avoidance Scale[31]). Outcomes on physical health included body-mass index (BMI), step count, body esteem (Body Esteem Scale for Adults and Adolescents[32]), substance use (Maudsley Addiction Profile[33]), and overall physical health (Patient Health Questionnaire[34]). Outcomes on quality of life included recovery (Questionnaire about the Process of Recovery[35]) and quality of life (Recovering Quality of Life[36] and Euroqol 5D questionnaire[37]). Outcomes related to service use (CSRI[38]) and medication and hospital admissions (from electronic medical records) were also recorded. The stress subscale of the DASS-21 was recorded for completeness. The CAARMS, CSSRS, time budget, and CSRI were administered by assessors. BMI was calculated from patient-reported height and weight. Step count was measured using an actigraph wearable device (Garmin Vivofit 4; Garmin,

Olathe, KS, USA). All other measures were self-reported by patients. All clinical outcome measures were collected at each assessment timepoint. A summary of all outcome measures is provided in the protocol (appendix 1 pp 12–13).

Safety outcomes included patient-reported adverse events during trial participation. At the end of trial participation, we checked electronic medical records for serious adverse events, defined as any untoward medical occurrence that results in death, is life-threatening, requires or prolongs hospital admission, or results in persistent or clinically significant disability or incapacity. We also recorded formal complaints about therapy, and transition to psychosis. An independent data monitoring and ethics committee chair rated whether any serious adverse event was related to the trial procedures or intervention.

Statistical analysis

The sample size was calculated in accordance with the feasibility aims of the trial. A sample size of 20 participants per randomised group (40 in total across the study) was calculated to be sufficient to estimate a recruitment rate of 50% with 95% CI 35–65 and a retention rate of 80% at 3 months and 9 months with 95% CI 65–90 (PASS software version 12). This sample size was also determined to be sufficient to estimate the variability of outcome measures for future sample size calculations, with 12 per arm sufficient for estimation of the variability for the purpose of sample size calculations.[48] The trial was not powered to detect a significant difference between treatment groups.

For the feasibility markers, analysis was descriptive in nature and no hypothesis testing was done. Numbers and proportions were presented for binary feasibility measures (ie, recruitment and retention, uptake of treatment, and data completion) overall and by randomised group. Continuous measures were presented as the mean (SD), or as the median (IQR) when required. For feasibility markers, there were prespecified progression criteria to inform the design of a future definitive trial including stop, amend, or proceed. For recruitment, the proceed criterion for a future trial was a mean rate of at least two participants per month. For treatment uptake, consent by eligible participants, retention, and data collection, the proceed criterion for a future trial was a rate of at least 75%.

For preliminary clinical outcomes, statistical analysis was restricted to the primary outcome and three key secondary outcomes, as outlined in the statistical analysis plan (appendix 2 pp 9, 19–20). Linear mixed-effects models were used, with baseline score of the outcome of interest, time, treatment group, and a time by treatment group interaction included as fixed effects and participant as a random effect. We report the treatment effect estimate as the adjusted mean difference between groups with 95% CIs. In addition, we report estimates for Cohen's *d* effect sizes, at each timepoint, as the adjusted mean difference of the outcome (between the groups) divided by the baseline SD of the outcome for both groups combined. An effect size of 0·2 is considered a small effect, 0·5 a medium effect, and 0·8 or higher a large effect.[49,50] Results were graphically presented in a forest plot. No p-values are reported for any outcomes as this is a feasibility trial. For other clinical outcomes, the analysis was descriptive with no hypothesis testing.

Receipt of the intervention, participation to follow-up, and adverse events were fully documented among all recruited participants. Clinical outcomes are reported by randomised group for all participants randomly assigned (intention-to-treat analysis). All participants with

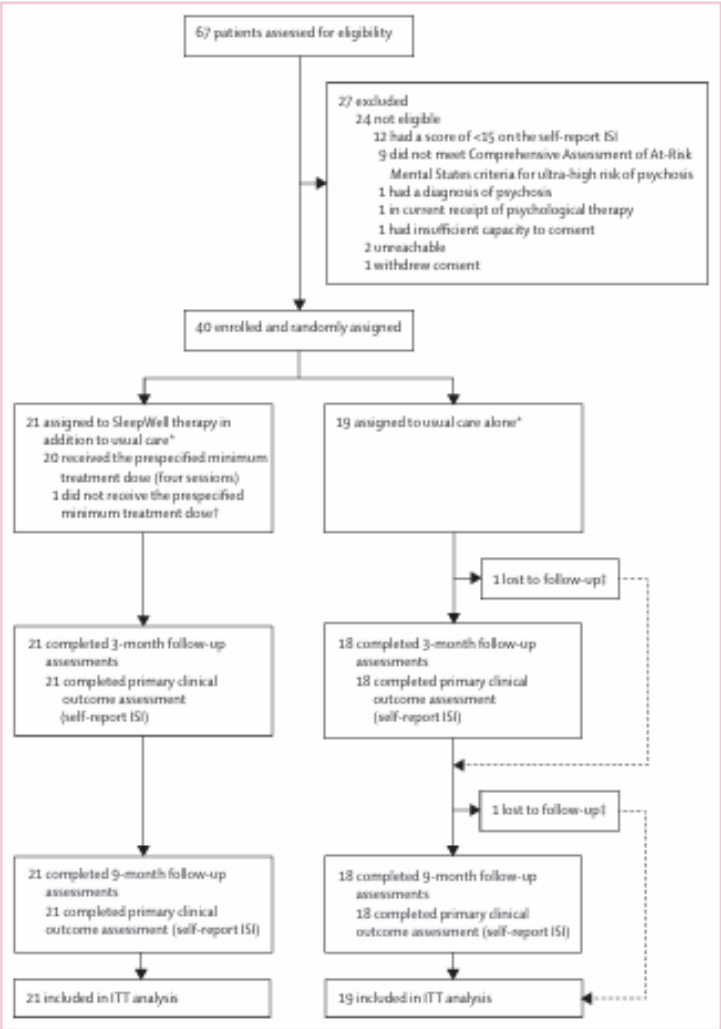

Figure 1: Trial profile
ISI=Insomnia Severity Index. ITT=intention-to-treat. *Summaries of the usual care received are provided in appendix 3 (pp 56–57). †Patient received two sessions. ‡Two separate participants; each of these participants provided data at one follow-up timepoint, meaning 19 participants were included in the ITT analysis overall.

available data were included in all analyses of feasibility and clinical outcomes in the treatment group to which they were randomised. Safety was assessed in all randomly assigned participants.

All analyses were done in Stata (version 16.1). The forest plot was produced in Microsoft Excel (version 2306). The statistical analysis plan (appendix 2) was approved by the data monitoring and ethics committee before any inspection of post-randomisation data. A full statistical report is provided in appendix 3.

See Online for appendix 3

	Usual care alone (n=19)	SleepWell therapy plus usual care (n=21)	All participants (n=40)
Age, years	16·8 (2·8; 14–22)	17·0 (2·2; 14–23)	16·9 (2·5; 14–23)
Gender			
Female	8 (42%)	11 (52%)	19 (48%)
Male	9 (47%)	10 (48%)	19 (48%)
Other	2 (11%)	0	2 (5%)
Ethnicity			
White	15 (79%)	17 (81%)	32 (80%)
Black British	0	1 (5%)	1 (3%)
Black Caribbean	0	1 (5%)	1 (3%)
Indian	1 (5%)	0	1 (3%)
Pakistani	1 (5%)	0	1 (3%)
Other	2 (11%)	2 (10%)	4 (10%)
Age at first contact with mental health services, years	14·5 (3·2; 7–21)	15·0 (3·3; 10–23)	14·8 (3·2; 7–23)
Living situation			
Living with parents or caregivers	17 (89%)	18 (86%)	35 (88%)
Living with partner	1 (5%)	2 (10%)	3 (8%)
Living with others	1 (5%)	0	1 (3%)
Missing	0	1 (5%)	1 (3%)
Employment type			
Full-time school or college student	11 (58%)	16 (76%)	27 (68%)
Higher education institution student or full-time training	2 (11%)	1 (5%)	3 (8%)
Employed full-time (paid)	2 (11%)	3 (14%)	5 (13%)
Employed part-time (paid)	1 (5%)	0	1 (3%)
Unemployed (receiving state benefits)	0	1 (5%)	1 (3%)
Unemployed (not receiving state benefits)	2 (11%)	0	2 (5%)
Other	1 (5%)	0	1 (3%)
Currently prescribed psychotropic medication			
Individuals prescribed psychotropic medication	7 (37%)	10 (48%)	17 (43%)
Mean number of prescribed psychotropics	1·6 (0·5)	1·3 (0·5)	1·4 (0·5)
Type of psychotropic medication prescribed			
Antipsychotic medication	1 (5%)	0	1 (3%)
Antidepressant medication	7 (37%)	10 (48%)	17 (43%)
Anxiolytic medication	0	0	0
Mood stabiliser	1 (5%)	0	1 (3%)
Hypnotic medication	2 (11%)	2 (10%)	4 (10%)

Data are n (%), mean (SD; range), or mean (SD). Percentages do not always add up to 100% due to rounding.

Table 1: Baseline characteristics

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

Recruitment took place from Nov 18, 2020, to Jan 26, 2022 (including approximately 48 weeks with restrictions on face-to-face contact due to the COVID-19 pandemic), with final follow-up data collected on Sept 21, 2022. Of 163 patients referred to the study, 67 patients completed screening, and 40 were enrolled and randomly assigned to the SleepWell intervention in addition to usual care (n=21) or usual care alone (n=19; figure 1).

At baseline, the mean age of participants was 16·9 years (SD 2·5; range 14–23). Most participants identified as either female (n=19, 48%) or male (n=19, 48%). 32 (80%) participants were White, 35 (88%) were living with their parents or caregivers, 27 (68%) were a full-time school or college student, and 17 (43%) were currently being prescribed psychotropic medication, predominantly antidepressants (table 1). ISI scores at baseline indicated that most participants had moderate insomnia (mean 18·9 [SD 3·0]), with nine (23%) participants in the severe range (score ≥22). Measured on the DASS-21, participants had levels of depression (mean 29·0 [SD 11·4]) and anxiety (mean 23·3 [SD 11·6]) in the extremely severe range (score of ≥28 on the depression scale and ≥20 on the anxiety scale),[12] and, measured on the R-GPTS, levels of paranoia (R-GPTS part A, ideas of reference: mean 18·2 [SD 9·1]; and R-GPTS part B, ideas of persecution: mean 16·9 [SD 11·80]) in the moderately severe range (score of 16–20 [part A] and 11–17 [part B]).[11] Measured on the SPEQ-H, 26 (65%) participants heard voices at least once a week. 20 (50%) participants were having active suicidal ideation, as measured on the CSSRS.

All progression criteria to inform future trial design related to rates of recruitment, retention, data collection, and treatment uptake were achieved. 67 patients were screened for eligibility, and 40 (60%) were enrolled at a mean rate of 2·85 participants per month. No eligible individuals declined enrolment into the trial. Two eligible participants were unreachable after screening. One eligible participant withdrew consent before randomisation. No participants withdrew after randomisation. All participants provided data on at least one follow-up visit at 3 and 9 months. However, one assessment was missed at each follow-up timepoint, giving a follow-up rate of 98%. Of 163 patients referred, 116 (71%) referrals were received from Oxford Health NHS Foundation Trust and 47 (29%) from Berkshire Healthcare NHS Foundation Trust. Most referrals were received from EIS (n=104, 64%) or CAMHS (n=39, 24%), with the remaining referrals from other adult mental health services (n=9 [5%] from IAPT). The rates of recruitment by service type and month are included in appendix 3

(p 39). Among the 40 enrolled patients, 39 (98%) completed the primary clinical outcome assessment at each follow-up timepoint. All participants completed the primary clinical outcome assessment on at least one follow-up visit. For other clinical outcome measures at 3 months, assessments were completed by at least 35 (88%) participants per measure for self-report clinical assessments, with lower numbers providing data for the sleep diary (n=26, 65%), step count with the actigraph device (n=26, 65%), and BMI (n=30, 75%). Clinician assessments were completed by at least 34 (85%) participants per measure. At 9 months, data completion rates remained high (≥37 participants per measure; ≥93%) for self-report measures. At baseline, most clinical assessments were completed remotely (either fully, n=25, 63%; or partially, n=12, 30%). The mean time to complete the assessments, including self-report and clinician-administered items (excluding the sleep diary and actigraphy) was 171·8 min (SD 55·0) at baseline, 117·9 min (46·8) at 3 months, and 104·7 min (43·9) at 9 months. Service use data are presented in appendix 3 (pp 46, 56–57).

Among participants assigned to the SleepWell intervention, 20 of 21 received the prespecified minimum treatment dose of at least four sessions of the intervention, representing a treatment uptake of 95%. The remaining patient received two sessions. The mean number of sessions attended was 7·71 (SD 2·12; range 2–12; n=21). The mean number of sessions missed (not attended or cancelled) was 1·19 (1·69). In total, 162 sessions were provided. These sessions were held at the patient's home (n=54 sessions, 33%), in the clinic (n=43, 27%), or remotely (n=65, 40%). Remote sessions were held by videocall (n=56, 86% of 65 remote sessions, 35% of 162 total sessions) or by telephone (n=9, 14% of remote sessions, 6% of total sessions). Personal protective equipment was used in all in-person sessions. All participants received between-session contact as part of the therapy. The frequency of contact was determined by patient choice. The median treatment acceptability score, measured on the AARP, was 48 (IQR 46–48; n=17; table 2). Within the treatment, all participants collaboratively developed a maintenance cycle formulation of the sleep problem and received psychoeducation about sleep. The most common active treatment techniques were establishing a sleep window (ie, the key anchor times for sleep and wakefulness) coupled with creating a wind-down routine to prepare for sleep and a rise-up routine to promote being active in the morning (n=20 [95%]). All participants engaged in active practice of the treatment techniques between sessions on at least one occasion (with implementation of techniques reviewed in 125 [77%] of 162 sessions).

We summarised preliminary clinical outcome data on the primary outcome (insomnia, assessed with the ISI) and key secondary outcomes (psychotic experiences, measured with the CAARMS and R-GPTS; and affective symptoms, measured with the DASS-21; table 3, figure 2). Available data in the ITT population were assessed. Compared with the usual care alone group, the SleepWell therapy group had notable reductions in insomnia severity, with large effect size estimates, at 3 months (ISI adjusted mean difference −8·12 [95% CI −11·60 to −4·63], Cohen's *d*=−2·67 [95% CI −3·81 to −1·52]) and 9 months (ISI adjusted mean difference −5·83 [−9·31 to −2·35], Cohen's *d*=−1·91 [−3·06 to −0·77]). At the post-intervention follow-up (3 months), 15 (71%) of 21 participants in the SleepWell treatment group had an ISI score lower than the cut-off for insomnia (score <8), compared with two (11%) of 18 participants in the control group. The SleepWell intervention was also associated with reductions in depression and anxiety (DASS-21), and paranoia (RGPTS-A and RGPTS-B), although confidence intervals crossed the null at 3 months (table 3, figure 2). Larger effect sizes were observed at 9 months for these measures and confidence intervals did not cross the null. Although small-to-medium effect sizes were observed for the effect of the SleepWell intervention on CAARMS score, the confidence intervals at both timepoints were wide and covered a range from potentially increasing to decreasing scores. Descriptive statistics for secondary clinical outcome measures are provided in table 4.

During the 9 months of follow-up, six participants had a total of eight adverse events. Three events were reported in two (11%) of 19 participants (both male participants) in the usual care group, and five events were reported in four (19%) of 21 participants (three female participants, one male participant) in the SleepWell intervention group. Three of the events in the SleepWell group occurred during the period of SleepWell provision. There was one serious adverse event (SleepWell group; female participant) which involved hospital admission for a physical health problem during

	n	Minimum rating by patients	Maximum rating by patients	Mean (SD)
This was an acceptable treatment for me	17	4	6	5·71 (0·686)
This treatment has been effective in alleviating my sleep problems	17	3	6	5·59 (0·870)
My sleep problems were severe enough to justify the use of the treatment	17	4	6	5·65 (0·606)
I would be willing to undergo this treatment again	17	4	6	5·82 (0·529)
This treatment did not have bad side-effects	17	4	6	5·59 (0·712)
I liked this treatment	17	4	6	5·76 (0·664)
The treatment was a good way to handle my sleep problems	17	4	6	5·76 (0·664)
Overall, the treatment was helpful	17	5	6	5·88 (0·332)
Treatment Acceptability scale totals*	17	33	48	45·76 (4·409)

Treatment acceptability was measured on the Abbreviated Acceptability Rating Profile.[31] Each item is rated on a scale of 1–6, giving an overall total maximum score of 48. *Median total score was 48 (IQR 46–48).

Table 2: SleepWell treatment acceptability

	Usual care alone (n=19)	SleepWell therapy plus usual care (n=21)	Adjusted mean difference (95% CI)*	Standardised effect size, Cohen's d (95% CI)
Insomnia Severity Index total score				
Baseline	18·7 (3·3); n=19	19·2 (2·8); n=21	..	..
3 months	14·3 (5·8); n=18	6·3 (4·9); n=21	−8·12 (−11·60 to −4·63)	−2·67 (−3·81 to −1·52)
9 months	13·9 (5·8); n=18	8·3 (6·3); n=21	−5·83 (−9·31 to −2·35)	−1·91 (−3·06 to −0·77)
Comprehensive Assessment of At-Risk Mental States symptom severity total score				
Baseline	45·4 (12·1); n=19	50·8 (11·2); n=21	..	..
3 months	44·6 (21·6); n=16	42·2 (20·9); n=19	−6·83 (−20·60 to 6·94)	−0·58 (−1·75 to 0·59)
9 months	39·3 (26·6); n=18	38·8 (21·4); n=20	−3·44 (−16·81 to 9·92)	−0·29 (−1·43 to 0·84)
R-GPTS-A (ideas of reference) total score				
Baseline	17·6 (9·5); n=19	18·7 (8·9); n=21	..	..
3 months	15·9 (11·1); n=17	13·2 (8·9); n=20	−4·70 (−10·03 to 0·63)	−0·52 (−1·10 to 0·07)
9 months	15·9 (11·2); n=18	10·4 (9·5); n=21	−5·90 (−11·11 to −0·69)	−0·65 (−1·22 to −0·08)
R-GPTS-B (ideas of persecution) total score				
Baseline	14·7 (11·9); n=19	18·9 (11·7); n=21	..	..
3 months	14·5 (13·3); n=17	14·4 (11·7); n=20	−4·51 (−10·99 to 1·97)	−0·38 (−0·93 to 0·17)
9 months	15·5 (15·5); n=18	10·3 (10·1); n=21	−7·73 (−14·07 to −1·39)	−0·65 (−1·19 to −0·12)
DASS-21 depression scale total score				
Baseline	27·5 (12·4); n=19	30·4 (10·5); n=21	..	..
3 months	21·3 (14·6); n=17	19·5 (13·4); n=19	−4·00 (−11·47 to 3·47)	−0·35 (−1·01 to 0·31)
9 months	19·8 (14·8); n=16	14·7 (10·2); n=21	−7·66 (−15·09 to −0·22)	−0·67 (−1·33 to −0·02)
DASS-21 anxiety scale total score				
Baseline	20·3 (12·6); n=19	26·0 (10·1); n=21	..	..
3 months	17·9 (14·0); n=17	15·9 (13·3); n=19	−6·22 (−12·60 to 0·16)	−0·54 (−1·09 to 0·01)
9 months	18·6 (11·4); n=16	13·7 (11·0); n=21	−9·55 (−15·91 to −3·19)	−0·83 (−1·38 to −0·28)

Scores are mean (SD), with number of patients with available data shown. R-GPTS=Revised Green et al Paranoid Thoughts Scale. DASS-21=Depression Anxiety Stress Scales–21 items. *SleepWell therapy plus usual care versus usual care alone; mean difference was estimated from a linear mixed-effects model adjusting for outcome measure at baseline, time, treatment group, and a time by treatment group interaction as fixed effects, and participant as a random effect; standardised effect size (Cohen's *d*) was calculated as the estimated mean difference divided by baseline standard deviation.

Table 3: **Summary statistics for primary and key secondary clinical outcome data**

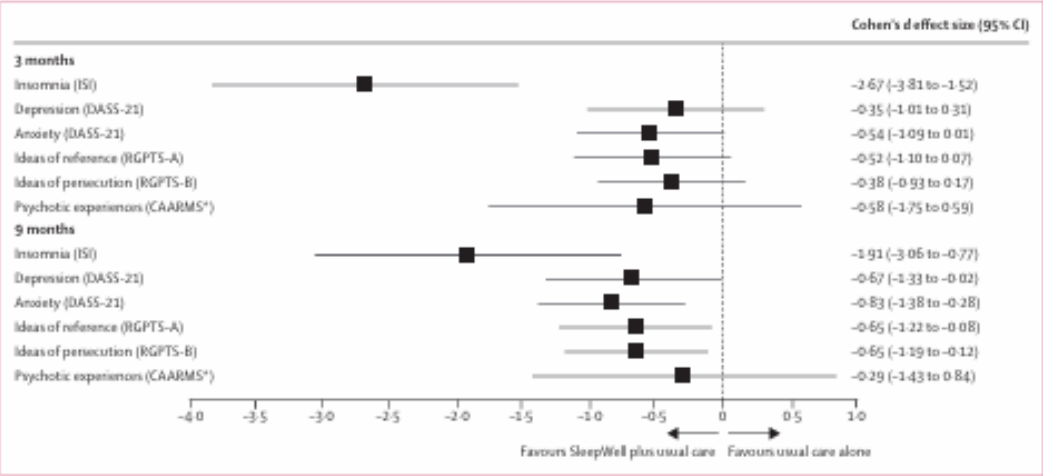

Figure 2: **Forest plot of Cohen's d effect sizes**
ISI=Insomnia Severity Index. DASS-21=Depression Anxiety Stress Scales–21 items. R-GPTS-A=Revised Green et al Paranoid Thoughts Scale, part A. R-GPTS-A=Revised Green et al Paranoid Thoughts Scale, part B. CAARMS=Comprehensive Assessment of At-Risk Mental States. *Symptom severity (Global Rating Scale) on CAARMS.

	Usual care alone (n=19)	SleepWell therapy plus usual care (n=21)
Sleep variables		
Sleep-50 Circadian Rhythm Disruption subscale total score		
Baseline	6·8 (2·0); n=19	7·4 (2·3); n=21
3 months	6·9 (2·5); n=17	4·6 (1·7); n=19
9 months	6·4 (2·2); n=17	6·2 (2·5); n=21
Total sleep time per night, minutes		
Baseline	407·1 (124·7); n=14	387·3 (93·0); n=15
3 months	447·3 (119·1); n=14	461·4 (83·2); n=12
9 months	460·8 (54·8); n=13	497·2 (65·3); n=13
Sleep onset latency per night, minutes		
Baseline	68·1 (42·2); n=14	72·0 (61·2); n=15
3 months	60·2 (77·1); n=14	36·7 (27·2); n=12
9 months	36·9 (26·4); n=13	24·8 (16·0); n=13
Sleep efficiency		
Baseline	63·7 (16·6); n=14	63·9 (17·0); n=14
3 months	68·6 (24·0); n=14	79·4 (10·5); n=11
9 months	75·8 (9·8); n=13	81·2 (9·4); n=12
Sleep regularity ≤1 h		
Baseline	7 (50%); n=14	7 (50%); n=14
3 months	6 (50%); n=12	9 (75%); n=12
9 months	7 (54%); n=13	6 (46%); n=13
Psychiatric symptom variables		
Specific Psychotic Experiences Questionnaire–Hallucinations subscale total score		
Baseline	23·8 (9·2); n=19	23·8 (9·6); n=21
3 months	18·3 (12·4); n=18	18·8 (12·2); n=20
9 months	16·7 (14·0); n=18	14·6 (10·5); n=21
Černis Felt Sense of Anomaly total score		
Baseline	74·0 (31·8); n=19	75·8 (41·2); n=21
3 months	65·6 (38·4); n=17	63·2 (37·0); n=19
9 months	60·7 (41·4); n=17	53·0 (41·2); n=21
Columbia Suicide Severity Rating Scale score (most severe suicidal ideation)		
Baseline	1·5 (1·7); n=19	2·1 (1·5); n=21
3 months	1·4 (1·9); n=16	1·2 (1·3); n=18
9 months	1·0 (1·6); n=16	0·9 (1·3); n=18
Dunn Worry Questionnaire total score		
Baseline	29·8 (9·7); n=19	34·8 (6·5); n=21
3 months	24·9 (13·5); n=17	25·9 (12·3); n=19
9 months	26·2 (10·7); n=17	21·4 (12·3); n=21
Brief Core Schema Scales–negative-self subscale total score		
Baseline	12·6 (8·0); n=19	15·2 (5·4); n=21
3 months	10·4 (7·2); n=17	9·5 (6·8); n=19
9 months	9·7 (6·6); n=17	7·9 (6·1); n=21
Brief Core Schema Scales–positive-self subscale total score		
Baseline	6·7 (4·2); n=19	5·2 (4·2); n=21
3 months	7·9 (5·2); n=17	9·8 (4·5); n=19
9 months	9·1 (6·1); n=17	10·2 (5·6); n=21
(Table 4 continues in next column)		

	Usual care alone (n=19)	SleepWell therapy plus usual care (n=21)
(Continued from previous column)		
Activity, social functioning, and recovery measures		
Time budget total score		
Baseline	63·2 (19·5); n=18	75·5 (14·3); n=21
3 months	63·3 (20·0); n=16	81·4 (11·3); n=19
9 months	69·7 (17·6); n=15	74·5 (14·0); n=18
Work and Social Adjustment Scale total score		
Baseline	22·4 (9·5); n=19	27·4 (6·0); n=21
3 months	22·4 (13·0); n=17	18·3 (12·0); n=19
9 months	19·8 (9·5); n=19	11·1 (9·2); n=20
Oxford Agoraphobic Avoidance Scale total avoidance score		
Baseline	2·0 (2·2); n=17	3·0 (2·4); n=21
3 months	2·4 (2·3); n=17	2·2 (2·4); n=19
9 months	1·3 (1·6); n=17	1·1 (1·9); n=20
Oxford Agoraphobic Avoidance Scale total distress score		
Baseline	35·9 (19·7); n=18	42·8 (23·2); n=21
3 months	35·6 (20·5); n=17	31·2 (23·9); n=19
9 months	30·9 (20·5); n=15	20·4 (19·1); n=21
Daily step count		
Baseline	4823 (3685·0); n=16	6700 (3746·7); n=16
3 months	6169 (1958·2); n=11	5527 (3137·4); n=15
9 months	7649 (4792·1); n=13	7402 (5242·0); n=14
Questionnaire about the Process of Recovery total score		
Baseline	28·2 (13·5); n=19	28·9 (13·5); n=21
3 months	31·2 (13·7); n=17	34·7 (11·6); n=19
9 months	31·9 (11·1); n=17	36·6 (10·7); n=21
Recovering Quality of Life total score		
Baseline	28·5 (16·3); n=19	20·3 (8·1); n=21
3 months	35·4 (17·4); n=16	39·8 (18·8); n=19
9 months	32·1 (17·2); n=17	44·6 (14·3); n=21

Data are mean (SD) or n (%), with number of patients with available data shown. Other preliminary clinical outcomes are provided in appendix 3 (pp 54–57).

Table 4: Descriptive statistics for secondary clinical outcomes

the intervention period. No adverse events were classed as being related to trial treatment or procedures. One patient transitioned to psychosis, in the usual care alone group, which was deemed to be unrelated to trial involvement.

Discussion

To our knowledge, this is the first randomised controlled trial of a sleep treatment in young people at ultra-high risk of psychosis. Overall, the study indicates the feasibility of testing a psychological sleep intervention adapted for this population. Recruitment targets were met, despite the additional challenges of the COVID-19 pandemic. Retention was high with all participants providing follow-up data. Uptake and acceptability of the therapy were also very high. Furthermore, we found preliminary indications of clinical benefit. After the brief targeted psychological intervention, we observed large reductions in sleep problems, which were sustained at follow-up. There were also reductions in ratings of depression, anxiety, and paranoia at follow-up.

The uptake of treatment and attendance at therapy sessions were high. All but one participant received the minimum treatment dose of four sessions. The assessments and therapy were delivered in a hybrid format including both remote and in-person meetings. Although this hybrid approach was initially a response to the restrictions of the COVID-19 pandemic, treatment uptake and trial retention remained high during remote contact, and this hybrid approach is likely to be incorporated in future service delivery models, which has the potential to increase the range of options available to patients. We also aimed to offer flexibility and patient choice in the timings of sessions, which might be facilitated by online delivery. Overall treatment acceptability and engagement were high. The modular treatment could be personalised following assessment and formulation. The most common treatment techniques were establishing a sleep window and creating wind-down and rise-up routines. These techniques address circadian alignment and hyperarousal. All participants engaged in active practice of the treatment techniques. This finding is consistent with previous qualitative accounts of the SleepWell therapy in which young patients described a process of "trying things out" and valuing the experience.[5]

The preliminary clinical effects of the intervention on sleep are consistent with the large effects reported in numerous trials of CBT for insomnia. For example, in a meta-analysis of 87 trials of CBT for insomnia, the reported effect size for improvement in ISI was large (Hedge's g=0·98).[51] Although fewer studies have been done in the adolescent population, a meta-analysis of nine randomised controlled trials showed similar large effect sizes for the effect of CBT for insomnia on global sleep quality (Cohen's d=0·92).[52] Large effects have consistently been reported when treating sleep problems across the spectrum of severity of psychosis (effect size range d=0·9–1·9).[9,14,15] Although only preliminary findings, the effect sizes in the current study are larger than those reported previously, and therefore encouraging. The effects of CBT for insomnia on depression are well recognised,[53] with the approach recently adapted for adolescents.[54] The meta-analysis of trials of CBT for insomnia in adolescents also reported outcomes on depression and anxiety, with larger effects at later follow-up,[52] which is again consistent with findings in the current study and further indicates the potential mechanistic effect of improving sleep on mental health. The preliminary outcomes in relation to psychotic experiences are encouraging, especially given the small size of the study. The levels of paranoia in the participant group at baseline were similar to those seen in patients with a diagnosis of psychosis (eg, the gameChange trial[55]). The size of treatment effects on paranoia in the current trial is promising. The preliminary treatment effects on psychotic experiences, depression, and anxiety were larger at the later follow-up (9 months) compared with the post-intervention follow-up (3 months). This finding is consistent with the theoretical rationale that sleep disruption is a causal factor in the occurrence of these mental health problems, and these affective symptoms (ie, anxiety and depression) might mediate the relationship between sleep disturbance and psychotic experiences.[6–8] A definitive trial with embedded mediation and moderation tests is required to identify the wider effects of the SleepWell intervention (including preventative effects on psychotic experiences), how it works, and for whom it might work best.

The main limitation when considering the potential clinical effects is that this feasibility trial was not designed or powered to detect clinical effects. No active comparison was used to control for elements of the treatment that might have benefit, such as contact time with a clinician. This design gives an overall indication of the benefit of the approach when added to standard care, but not which elements are necessary or if another treatment might be more effective. Notably, no specific at-risk mental health services for young people at ultra-high risk of psychosis were available at the recruiting sites, and therefore usual care was limited. Recruitment was predominantly via EIS and CAMHS. Working with CAMHS has been identified as a potential avenue for early preventative interventions for psychosis.[56] Given the drive to increase current service provision for young people at ultra-high risk of psychosis in England[57] in consideration of the often sparse availability of services for this group, identifying brief and effective implementable treatments should be a key priority for policy makers. In accordance with our focus on subjective experiences of sleep disruption and psychotic experiences, we primarily used self-report assessments. We used actigraphic measurements as a marker of activity due to the potential physical health benefits of improved sleep, but remain cautious about the precision of actigraphy to determine sleep-wake parameters. The study was done across two NHS trusts in England and the participants will not be representative of all young people at ultra-high risk of psychosis or accessing mental health services.

In conclusion, the outcomes of this trial are promising regarding the potential benefits of treating sleep problems at the early stages of psychosis. A definitive trial, with embedded mediation and moderation, is now needed to assess the clinical benefits suggested in this feasibility study. Such a trial by our team is due to begin in 2024.

SleepWell lived experience advisory group
Abreen Rebello, Steven Evans, Jummy Otaiku, and Tom Sharpe (McPin Foundation, London, UK).

Contributors

FW was the chief investigator and wrote the first draft of the manuscript. FW and DF conceived the study and led the design of the trial and treatment. TK led the Patient and Public Involvement work, including facilitating the SleepWell lived experience advisory group. The SleepWell lived experience advisory group provided lived

experience expertise that informed the design and delivery of the trial. EC coordinated the trial. EC, RD, and FW delivered the treatment. FW provided treatment supervision. LJ and DM were the local clinical service leads. EI recruited participants and conducted assessments. EC and FW led the data management. RS and NW did the statistical analysis. L-MY led the statistical analysis and input from the Oxford Primary Care Clinical Trials Unit. All authors had full access to all the data in the study. FW, RS, and NW accessed and verified the data and take responsibility for the integrity of the data and the accuracy of the data analysis. All authors contributed to critical review and editing of the manuscript and had final responsibility for the decision to submit for publication.

Declaration of interests

We declare no competing interests.

Data sharing

Deidentified participant data will be available with publication in anonymised form from the corresponding author (felicity.waite@psy.ox.ac.uk) on reasonable request (including a study proposal), subject to review and contract with Oxford Health National Health Service (NHS) Foundation Trust.

Acknowledgments

The trial was funded by the NHS Research for Patient Benefit programme (grant reference number NIHR200481). The trial was also supported by the National Institute for Health and Care Research (NIHR) Oxford Health Biomedical Research Centre (grant numbers BRC-1215–2000 and NIHR203316). FW is supported by a Wellcome Trust Clinical Doctoral Fellowship (award number 102176/B/13/Z). DF is an NIHR Senior Investigator. The views expressed are those of the authors and not necessarily those of the NIHR or the Department of Health and Social Care. We thank the participants who took part in this study. We also thank members of the research team not listed as authors, including Sapphira McBride, Simone Saidel, Kira Williams, Helen Beckwith, and Ariane Beckley. We express our gratitude to The McPin Foundation in facilitating patient and public involvement, including Roya Kamvar and colleagues. We thank the independent members of the data monitoring and ethics committee, chaired by Matthew Broome, including Rory Byrne, Sophie Parker, and Natalie Rowland. We thank members of the Oxford Health NHS Foundation Trust research and development team, Nick Raven and Bill Wells; and members of the Berkshire Healthcare NHS Foundation Trust research and development team, Emma Donaldson and Rachel Stevenson. Finally, we would like to thank the clinical teams in the participating NHS trusts.

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2.2 Ethics approval: Health Research Authority

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

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19 August 2020

Dear Dr Waite

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Treating sleep problems in young people at ultra-high-risk of psychosis: a feasibility randomised controlled trial.**
IRAS project ID:	**281235**
REC reference:	**20/SC/0281**
Sponsor	**University of Oxford / Clinical Trials and Research Governance**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report

(including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **281235**. Please quote this on all correspondence.

Yours sincerely,
Joanna Strickland
Approvals Specialist

Email: oxforda.rec@hra.nhs.uk

Copy to: *CTRG, Oxford*

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
Contract/Study Agreement template [mNCA 2018]	1	24 June 2020
Copies of advertisement materials for research participants [Leaflet]	1.0	01 July 2020
Copies of advertisement materials for research participants [Poster]	1.0	01 July 2020
Covering letter on headed paper [Covering Letter]		02 July 2020
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Sponsor Insurance]		29 July 2019
Interview schedules or topic guides for participants [Qualitative Interview Schedule]	1.0	01 July 2020
IRAS Application Form [IRAS_Form_03072020]		03 July 2020
IRAS Checklist XML [Checklist_03072020]		03 July 2020
IRAS Checklist XML [Checklist_17082020]		17 August 2020
Letter from funder [Funder Letter]		15 April 2020
Letter from sponsor [Sponsor Letter]		02 July 2020
Non-validated questionnaire [Demographics]		
Organisation Information Document [amended]	1	17 July 2020
Other [Response to REC and HRA review]		17 August 2020
Other [Front Sheet Assessment Pack]	1.0	01 July 2020
Other [Sleep Diary]	1.0	01 July 2020
Other [Actigraphy]	1.0	01 July 2020
Other [BMI]	1.0	01 July 2020
Other [Medical Record Data]	1.0	01 July 2020
Other [Treatment outcome ranking]	1.0	01 July 2020
Participant consent form [Assent Form - 14-15 years]	1.0	01 July 2020
Participant consent form [Consent Form - 16-25 years]	1.0	01 July 2020
Participant consent form [Consent Form - Parent/Guardian]	1.0	01 July 2020
Participant information sheet (PIS) [Participant Information Sheet - 16-25 years_clean]	1.1	17 August 2020
Participant information sheet (PIS) [Participant Information Sheet - 14-15 years-clean]	1.1	17 August 2020
Participant information sheet (PIS) [Participant Information Sheet - Parent/Guardian_clean]	1.1	17 August 2020
Research protocol or project proposal [Clinical Trial Protocol]	1.0	01 July 2020
Schedule of Events or SoECAT [SoECAT_authorised]	1.0	21 February 2019
Summary CV for Chief Investigator (CI) [CV]		01 July 2020
Validated questionnaire [ISI Screening Form]	1	01 July 2020
Validated questionnaire [ISI]	1	01 July 2020
Validated questionnaire [SPEQ]	1	01 July 2020
Validated questionnaire [R-GPTS]	1	01 July 2020
Validated questionnaire [CAARMS positive symptoms subscales]	1	01 July 2020
Validated questionnaire [DASS-21]	1	01 July 2020
Validated questionnaire [CSSRS]	1	01 July 2020
Validated questionnaire [CSSRS Self-Report]	1	01 July 2020
Validated questionnaire [SLEEP50-CRD]	1	01 July 2020

Validated questionnaire [PHQ-15]	1	01 July 2020
Validated questionnaire [Time Budget]	1	01 July 2020
Validated questionnaire [ReQol]	1	01 July 2020
Validated questionnaire [WSAS]	1	01 July 2020
Validated questionnaire [STOP BANG Screening Form]		
Validated questionnaire [CSRI]	1	01 July 2020
Validated questionnaire [CSRI Abbreviated]	1	01 July 2020
Validated questionnaire [MAP]	1	01 July 2020
Validated questionnaire [BCSS]	1	01 July 2020
Validated questionnaire [BESAA]	1	01 July 2020
Validated questionnaire [DWQ]	1	01 July 2020
Validated questionnaire [QPR]	1	01 July 2020
Validated questionnaire [CEFSA]	1	01 July 2020
Validated questionnaire [SR O-BAT]	1	01 July 2020
Validated questionnaire [Sleepiness Fatigue Scale]	1	01 July 2020
Validated questionnaire [EQ 5D]	1	01 July 2020
Validated questionnaire [Treatment Acceptability Scale]	1	01 July 2020

IRAS project ID	281235

Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pack expectations
There is one NHS site type acting as a recruitment site; performing the local research activities as stated in the SoECAT. Please note that the remit of HRA Approval is limited to the NHS involvement in the study. Research activity undertaken at non-NHS sites is therefore not covered and the research team should make appropriate alternative arrangements with relevant management at these organisations to conduct the research there. The duty of care for home visits lies with the University.	Research activities should not commence at participating NHS organisations in England or Wales prior to their formal confirmation of capacity and capability to deliver the study.	An Organisation Information Document has been submitted and the sponsor is intending to use a separate site agreement. The model non-commercial agreement 2018 is unmodified.	External funding has been secured from an NIHR RfPB grant and Oxford Health Biomedical Research Council. Funding is available to the NHS sites and will be made by Oxford University.	A Principal Investigator is expected to be in place at each NHS site to oversee the local research activities.	If not already in place, a letter of access is required for assessment of participants in NHS Mental Health clinical areas. Enhanced DBS check including debarred list and occupational health clearance is expected to be in place. Lone working policy applies.

Other information to aid study set-up and delivery

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales in study set-up.
The local research activity required is the database search. All other research activities will be performed by grant funded research staff.
The sponsor will provide training to all research staff. The Sponsor expects individuals involved in a study to be trained appropriately for their function. All staff will be trained appropriately, including GCP.
Children reaching majority during the study are to be reconsented.

2.3 Ethics approval: Confirmation of local Capacity and Capability – Oxford Health NHS Foundation Trust

NHS
Oxford Health
NHS Foundation Trust

Professor Andrea Cipriani
Associate Director of Research & Development
Warneford Hospital
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OX3 7JX

Email: research@oxfordhealth.nhs.uk

09.11.2020

Confirmation of Capacity and Capability

Re: Treating sleep problems in young people at ultra-high-risk of psychosis: a feasibility randomised controlled trial
Research and Development Reference: 15005
IRAS Reference: 281235
Research Ethics Committee Reference: 20/SC/0281
NIHR Portfolio Ref: 46331
Sponsor: University of Oxford

Dear Louise Johns,

On behalf of Oxford Health NHS Foundation Trust, I am pleased to confirm Trust Capacity and Capability for the above research as outlined in the application received.

Approved Documents

Protocol Version 1 dated 01/07/2020 is recognised as the most current to date.

The documents approved for use at this Trust are as listed in the following approval documents:

Health Research Authority Letter dated: 19/08/2020
Research Ethics Full Approval Letter dated: 17/08/2020

Any subsequent, relevant amendments are additionally included to date.

Metrics and Recruitment

First Participant target	Agreed Total recruitment target
Target date: 07/12/2020	Target: 20
	Recruitment Target date 31/12/2021

To comply with national research performance requirements the Trust will monitor and publish recruitment for your study:
1.Performance of the recruitment of the first participant.
2.Recruiting planned participants to time and target.

Recruitment of participants needs to be reported via the Siteline system. The R&D data manager will contact you to set this up in the coming weeks. Failure to report accruals may impact the ongoing approvals for this study.

Should you feel at any time that you will be unable to realistically achieve your contracted recruitment target, please get in touch with the Research Team on research@oxfordhealth.nhs.uk as soon as possible.

Conditions of Approval

The following conditions apply to this approval:

a) The study is conducted in compliance with all the relevant legislation and the relevant OHFT policies.
b) All staff working on the study have the appropriate training and experience and have responsibilities formally delegated to them.
c) Should you plan to leave your position in OHFT, you will notify R&D immediately of your plans, to enable discussions around the future of study conduct.
d) The Trust expects the named Principal Investigator to allocate regular support time to the study; this must be agreed with the research team prior to the study commencing. This may be reviewed by R&D at any time.
e) All relevant documents will be maintained and will be sent to research@oxfordhealth.nhs.uk, to facilitate compliance checks, formal audits and regulatory inspections.
f) You will notify R&D via the email above of any protocol amendments.
g) You will promptly inform R&D via the email above of the end of the study.

I wish you every success with the study.

Yours sincerely,



Professor Andrea Cipriani
Associate Director of Research & Development

2.4: Ethics approval: Confirmation of local Capacity and Capability – Berkshire Healthcare NHS Foundation Trust

Healthcare from the heart of your community

Berkshire Healthcare NHS
NHS Foundation Trust

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Date: 29th September 2020

Dear Dr Waite

RE: CONFIRMATION OF CAPACITY AND CAPABILITY

Study Title: SLEEPWELL: Treating sleep problems in young people at ultra-high risk of psychosis

BHFT REF: 2020-32 **IRAS Project ID**:281235 **Portfolio status:** Portfolio

I am pleased to confirm that Berkshire Healthcare NHS Foundation Trust (BHFT) has the capacity and capability to undertake the above named research study, as described in your Statement of Activities report. This confirmation is dependent on formal approval from the HRA, which includes a favourable ethical opinion from a National Research Ethics Service Committee if applicable. The HRA approved documents should be provided to us, and where appropriate, all localised patient facing documents.

Berkshire Healthcare NHS Foundation Trust agrees to start this study on 29/09/2020 as previously discussed with you. This confirmation of capacity and capability is dependent on you and the sponsor commencing the study within 3 months from the date of this letter. If the study does not commence by 29/12/2020 then please notify the R&D office as the Trust position may have changed and this confirmation of capacity and capability may need to be reassessed. This study ends on 01/11/2022.

Recruitment

NHS Trusts are required to meet and report on performance standards set against national recruitment targets, one of which is first participant recruited to a study. I can confirm that your first participant target recruitment date is 29/10/2020. In addition to this, a study is expected to recruit its target sample size within a pre-specified recruitment period. In the Organisation Information Document you state that the Trust's involvement in your study will end on 01/11/2022 and that a target recruitment of 15 participants is required. If you feel that you may not meet these targets please notify the R&D department immediately research@berkshire.nhs.uk

Access to NHS for Research Purposes

Completion of a Research Passport Application may be required for researchers who do not hold a substantive or honorary contract with an NHS organisation. Research activity should not take place at this site until either a Letter of Access or Honorary Research Contract has been issued for individuals where this applies. Please contact the R&D office to check if this is required.

From the **1 July 2015 Berkshire Healthcare NHS Foundation Trust** is a **smoke free** organisation.
To help protect our staff and people who use our services from the harmful effects of tobacco smoke, please do not smoke anywhere on our sites, or during appointments when our staff are at your home. If you would like support to quit please speak to your healthcare professional or contact **Smoke Free Life Berkshire** on **0800 622 6360** or text **QUIT** to **66777**

Governance & Compliance

It is the Trust's expectation that the study will comply with all applicable and relevant laws, such as the General Data Protection Regulation (GDPR) May 2018, the Human Tissue Act (2004), the Mental Capacity Act (2005) and adheres to the UK Policy Framework for Health and Social Care Research (2018), the principles of (ICH) Good Clinical Practice (GCP) and the NHS Confidentiality Code of Practice (Nov 2003) and if applicable the Clinical Trial regulations.

Berkshire Healthcare Foundation Trust R&D Website

In order to comply with the UK Policy Framework for Health and Social Care Research (2018) and your ethical approval we will list your study on our Trust's website.

Please note that the Trust, as host organisation, is required to monitor research to ensure compliance with the UK Policy Framework and other legal and/or regulatory requirements and you may be asked to provide access to authorised individuals from the R&D office for monitoring or audit purposes.

In working with the Trust there is an expectation that the following are provided to the R&D office in a timely manner;

- date of first participant recruited
- ongoing recruitment figures
- copy of reports to the HRA/REC
- any substantial or non-substantial changes relevant to the OHFT
- final report on completion of the study
- any publications arising from the study
- immediate notification of changes in involvement of key site personnel

If you wish to discuss this further, please do not hesitate to contact the R&D Office.

Kind regards



Stephen Zingwe

R&D Manager

From the **1 July 2015** Berkshire Healthcare NHS Foundation Trust is a **smoke free** organisation.
To help protect our staff and people who use our services from the harmful effects of tobacco smoke, please do not smoke anywhere on our sites, or during appointments when our staff are at your home. If you would like support to quit please speak to your healthcare professional or contact **Smoke Free Life Berkshire** on **0800 622 6360** or text **QUIT** to **66777**

2.5: CONSORT checklist

Supplementary table. CONSORT 2010 checklist (completed for manuscript submitted for publication)

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5
	2b	Specific objectives or hypotheses	6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	9
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	8
	6b	Any changes to trial outcomes after the trial commenced, with reasons	9
Sample size	7a	How sample size was determined	10
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	7
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	10
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	10
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	15
	13b	For each group, losses and exclusions after randomisation, together with reasons	15
Recruitment	14a	Dates defining the periods of recruitment and follow-up	10
	14b	Why the trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	17
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	15
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)	12; 18
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	NA
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	NA

Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	12
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	13
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	13
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	13
Other information			
Registration	23	Registration number and name of trial registry	6
Protocol	24	Where the full trial protocol can be accessed, if available	6
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	21

2.6 Therapy adherence tool

Sleep Well

UNIVERSITY OF OXFORD

Therapy session adherence

	Core CBT Techniques	
Code	**Technique**	**Present**
G1	Complete measures	☐
G2	Establish homework task	☐
G3	Review homework / progress	☐
G4	Active and purposeful engagement	☐
G5	Dealing with a distressing event from the past week	☐
G6	Enhancing motivation	☐
G7	Establishing blueprint	☐

	Sleep Techniques	
Code	**Technique**	**Present**
S1	Psychoeducation and normalising about sleep	☐
S2	Developing maintenance cycle formulation	☐
S3	Addressing sleep environment (including lifestyle factors)	☐
S4	Identifying and agreeing key anchor times	☐
S5	Wind down (including relaxation) and rise up routines	☐
S6	Stimulus control	☐
S7	Establishing daytime routine: increasing activity in line with circadian rhythm	☐
S8	Utilising actigraphy/ Garmin data	☐
S9	Addressing night-time worry	☐
S10	Managing nightmares and night-time awakenings	☐
S11	Coping with psychotic-like experiences which impact on sleep (e.g. occurring at night-time, using sleep as an escape)	☐
S12	Establishing the 'sleep team'	☐

Additional notes:

Homework tasks set:

2.7 Outcome measure: Insomnia Severity Index

Date:	D	D	/	M	M	/	Y	Y	Y	Y
Researcher:										
Pt ID:										
Ax Point:	BL			3M			9M			

Your sleep

The following questions ask about your **sleep** in the **past two weeks**.
For each question please circle the number that best describes your answer.

Sleep problem	None	Mild	Moderate	Severe	Very Severe
1. Difficulty falling asleep.	0	1	2	3	4
2. Difficulty staying asleep.	0	1	2	3	4
3. Problem waking up too early.	0	1	2	3	4

4. How satisfied/ dissatisfied are you with your current sleep pattern?

Very satisfied				Very dissatisfied
0	1	2	3	4

5. To what extent do you consider your sleep problem to interfere with your daily functioning (e.g. daytime fatigue, mood, ability to function at work/daily chores, concentration, memory, mood etc.).

Not at all interfering	A little	Somewhat	Much	Very much interfering
0	1	2	3	4

6. How noticeable to others do you think your sleep problem is in terms of impairing the quality of your life?

Not at all noticeable	Barely	Somewhat	Much	Very much noticeable
0	1	2	3	4

7. How worried/distressed are you about your current sleep problem?

Not at all worried	A little	Somewhat	Much	Very much worried
0	1	2	3	4

2.8 Outcome measure: Comprehensive Assessment of At Risk Mental States

1: Positive Symptoms

1.1 Unusual Thought Content

Delusional Mood and Perplexity ('Non Crystallized Ideas')	
• Have you had the feeling that something odd is going on that you can't explain? What is it like?	
• Do you feel puzzled by anything? Do familiar surroundings feel strange?	
• Do you feel that you have changed in some way?	
• *Do you feel that others, or the world, have changed in some way?*	

Ideas of Reference	
• Ideas of Reference: Have you felt that things that were happening around you had a special meaning, or that people were trying to give you messages? What is it like? How did it start?	

Bizarre Ideas ('Crystallized Ideas')	
• Made thoughts, feelings, impulses: Have you felt that someone, or something, outside yourself has been controlling your thoughts, feelings, actions or urges? Have you had feelings or impulses that don't seem to come from yourself?	
• Somatic Passivity: Do you get any strange sensations in your body? Do you know what causes them? Could it be due to other people or forces outside yourself?	
• Thought Insertion: Have you felt that ideas or thoughts that are not your own have been put into your head? How do you know they are not your own? Where do they come from?	
• Thought Withdrawal: Have you ever felt that ideas or thoughts are being taken out of your head? How does that happen?	
• Thought Broadcasting: Are your thoughts broadcast so that other people know what you are thinking?	
• Thoughts Being Read: Can other people read your mind?	

UNUSUAL THOUGHT CONTENT- GLOBAL RATING SCALE

0 Never, absent	1 Questionable	2 Mild	3 Moderate	4 Moderately severe	5 Severe	6 Psychotic and Severe
No unusual thought content.	Mild elaboration of conventional beliefs as held by a proportion of the population	Vague sense that something is different, or not quite right with the world, a sense that things have changed but not able to be clearly articulated. Subject not concerned/ worried about this experience.	A feeling of perplexity. A stronger sense of uncertainty regarding thoughts than 2.	Referential ideas that certain events, objects or people have a particular and unusual significance. Feeling that experience may be coming from outside the self. Belief not held with conviction, subject able to question. Does not result in change in behaviour.	Unusual thoughts that contain completely original and highly improbable material. Subject can doubt (not held with delusional conviction), or which the subject does not believe all the time. May result in some change in behaviour, but minor.	Unusual thoughts containing original and highly improbable material held with delusional conviction (no doubt). May have marked impact on behaviour.

Onset date: _____ ***Offset date:*** _____

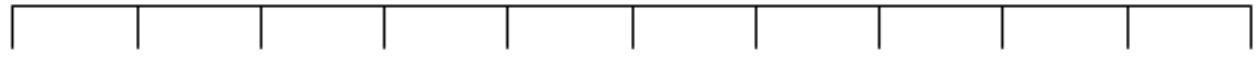
Frequency and Duration

0	1	2	3	4	5	6
Absent	Less than once a month	Once a month to twice a week – **less** than one hour per occasion	Once a month to twice a week – **more** than one hour per occasion **OR** 3 to 6 times a week - **less** than one hour per occasion	3 to 6 times a week - **more** than an hour per occasion **OR** daily – **less** than an hour per occ.	Daily – **more** than an hour per occ. **OR** several times a day	Continuous

Pattern of Symptoms

0	1	2
No relation to substance use noted	Occurs in relation to substance use and at other times as well	Noted only in relation to substance use

Level of Distress (In Relation to Symptoms)



0 **100**

Not At All Distressed Extremely Distressed

1.2 Non-Bizarre Ideas

Non-Bizarre Ideas ('Crystallized Ideas')	
• Suspiciousness, Persecutory Ideas: Has anybody been giving you a hard time or trying to hurt you? Do you feel like people have been talking about you, laughing at you, or watching you? What is it like? How do you know this?	
• Grandiose Ideas: Have you been feeling that you are especially important in some way, or that you have powers to do things that other people can't do?	
• Somatic Ideas: Have you had the feeling that something odd is going on with your body that you can't explain? What is it like? Do you feel that your body has changed in some way, or that there is a problem with your body shape?	
• Ideas of Guilt: Do you feel you deserve punishment for anything you have done wrong?	
• Nihilistic Ideas: Have you ever felt that you, or a part of you, did not exist, or was dead? Do you ever feel that the world does not exist?	
• Jealous Ideas: Are you a jealous person? Do you worry about relationships that your spouse/girlfriend/boyfriend has with other people?	
• Religious Ideas: Are you very religious? Have you had any religious experiences?	
• *Erotomanic Ideas: Is anyone in love with you? Who? How do you know this? Do you return his/her feelings?*	

NON-BIZARRE IDEAS - GLOBAL RATING SCALE

0 Never, absent	1 Questionable	2 Mild	3 Moderate	4 Moderately severe	5 Severe	6 Psychotic and Severe
No non-bizarre ideas.	Subtle changes that could be reality based. Eg. Very self-conscious.	Increased self-consciousness . Eg. Feeling that others look at the subject, or talk about the subject. Or feeling of increased self-importance. Subject able to question.	Odd or unusual thoughts but whose content is not entirely implausible- may be some logical evidence. More evidence than rating of 4. Content of thoughts not original i.e. jealousy, mild paranoia.	Clearly idiosyncratic beliefs, which although 'possible' have arisen without logical evidence. Less evidence than rating of 3. Eg. Thoughts that others wish the subject harm, which can be easily dismissed. Thoughts of having special powers, which can be easily dismissed.	Unusual thoughts about which there is some doubt (not held with delusional conviction), or which the subject does not believe all the time. May result in some change in behaviour, but minor.	Unusual thoughts containing original and highly improbable material held with delusional conviction (no doubt). May have marked impact on behaviour.

Onset date: _____ ***Offset date:*** _____

Frequency and Duration

0	1	2	3	4	5	6
Absent	Less than once a month	Once a month to twice a week – **less** than one hour per occasion	Once a month to twice a week – **more** than one hour per occasion **OR** 3 to 6 times a week - **less** than one hour per occasion	3 to 6 times a week - **more** than an hour per occasion **OR** daily – **less** than an hour per occ.	Daily – **more** than an hour per occ. **OR** several times a day	Continuous

Pattern of Symptoms

0	1	2
No relation to substance use/stress noted	Occurs in relation to substance use and at other times as well	Noted only in relation to substance use

Level of Distress (In Relation to Symptoms)

0 **100**

Not At All Distressed Extremely Distressed

1.3 Perceptual Abnormalities

Visual Changes	
• Distortions, illusions: Is there a change in the way things look to you? Do things somehow look different, or abnormal? Are there alterations in colour, or brightness of objects (things seeming brighter, or duller in colour)? Are there alterations in the size and shape of objects? Do things seem to be moving?	
• Hallucinations: Do you have visions, or see things that may not really be there? Do you ever seen things that others can't, or don't seem to? What do you see? At the time that you see these things, how real do they seem? Do you realise they are not real at the time, or only later?	
Auditory Changes	
• Distortions, illusions: Is there any change in the way things sound to you? Do things somehow sound different, or abnormal? Does your hearing seem more acute, or have increased sensitivity? Does your hearing seem muted, or less acute?	
• Hallucinations: Do you ever hear things that may not really be there? Do you ever hear things that other people seem not to (such as sounds or voices)? What do you hear? At the time you hear these things, how real do they seem? Do you realise they are not real at the time, or only later?	
Olfactory Changes	
• Distortions, illusions: Does your sense of smell seem to be different, such as more, or less intense, than usual?	
• *Hallucinations: Do you ever smell things that other people don't notice? At the time, do these smells seem real? Do you realise they are not real at the time, or only later?*	
Gustatory Changes	
• Distortions, illusions: Does your sense of taste seem to be different, such as more, or less intense, than usual?	

• *Hallucinations: Do you ever get any odd tastes in your mouth? At the time that you taste these things, how real do they seem? Do you realise they are not real at the time, or only later?*	
Tactile Changes	
• *Distortions, illusions, hallucinations: Do you ever get strange feelings on, or just beneath, your skin? At the time that you feel these things, how real do they seem? Do you realise they are not real at the time, or only later?*	
Somatic Changes	
• Distortions, illusions: Do you ever get strange feelings in your body (eg feel that parts of your body have changed in some way, or that things are working differently)? Do you feel/think that there is a problem with some part, or all of your body, i.e. that it looks different to others, or is different in some way? How real does this seem?	
• Hallucinations: Have you noticed any change in your bodily sensations, such as increased, or reduced intensity? Or unusual bodily sensations such as pulling feelings, aches, burning, numbness, vibrations?	

PERCEPTUAL ABNORMALITIES - GLOBAL RATING SCALE

0 Never, absent	1 Questionable	2 Mild	3 Moderate	4 Moderately severe	5 Psychotic but not severe	6 Psychotic and severe
No abnormal perceptual experience.		Heightened, or dulled perceptions, distortions, illusions (eg lights/ shadows). Not particularly distressing. Hypnogogic/ hypnopompic experiences	More puzzling experiences: more intense/vivid distortions/ illusions, indistinct murmuring, etc. Subject unsure of nature of experiences. Able to dismiss. Not distressing. Derealisation/ depersonalisn	Much clearer experiences than 3 such as name being called, hearing phone ringing etc, but may be fleeting/ transient. Able to give plausible explanation for experience. May be associated with mild distress.	True hallucinations i.e. hearing voices or conversation, feeling something touching body. Subject able to question experience with effort. May be frightening or associated with some distress.	True hallucinations which the subject believes are true at the time of, and after, experiencing them. May be very distressing

Onset date: _____ ***Offset date:*** _____

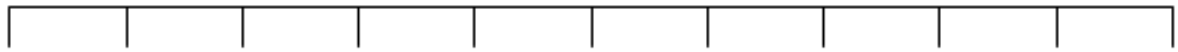
Frequency and Duration

0	1	2	3	4	5	6
Absent	Less than once a month	Once a month to twice a week – **less** than one hour per occasion	Once a month to twice a week – **more** than one hour per occasion **OR** 3 to 6 times a week - **less** than one hour per occasion	3 to 6 times a week - **more** than an hour per occasion **OR** daily – **less** than an hour per occ.	Daily – **more** than an hour per occ. **OR** several times a day	Continuous

Pattern of Symptoms

0	1	2
No relation to substance use noted	Occurs in relation to substance use and at other times as well	Noted only in relation to substance use

Level of Distress (In Relation to Symptoms)



0 **100**

Not At All Distressed Extremely Distressed

1.4 Disorganised Speech

Subjective Change:	
• Do you notice any difficulties with your speech, or ability to communicate with others?	
• Do you have trouble finding the correct word at the appropriate time?	
• Do you ever use words that are not quite right, or totally irrelevant?	
• Have you found yourself going off on tangents when speaking and never getting to the point? Is this a recent change?	
• Are you aware that you are talking about irrelevant things, or going off the track?	
• Do other people ever seem to have difficulty in understanding what you are trying to say/trouble getting your message across?	
• Do you ever find yourself repeating the words of others?	
• Do you ever have to use gesture or mime to communicate due to trouble getting your message across? How bad is this?	
• Does it ever make you want to stay silent and not say anything?	
Objective Rating of Disorganised Speech	
• Is it difficult to follow what the subject is saying at times due to using incorrect words, being circumstantial or tangential?	
• Is the subject vague, overly abstract or concrete? Can responses be condensed?	
• Do they go off the subject often and get lost in their words? Do they appear to have difficulty finding the right words?	
• Do they repeat words that you have used or adopt strange words (or 'non-words') in the course of regular conversation?	

DISORGANISED SPEECH- GLOBAL RATING SCALE

0 Never, absent	1 Questionable	2 Mild	3 Moderate	4 Moderately severe	5 Severe	6 Psychotic
Normal logical speech, no disorganisation, no problems communicating or being understood.		Slight subjective difficulties eg problems getting message across. Not noticeable by others.	Somewhat vague, some evidence of circumstantiality, or irrelevance in speech. Feeling of not being understood.	Clear evidence of mild disconnected speech and thought patterns. Links between ideas rather tangential. Increased feeling of frustration in conversation.	Marked circumstantiality, or tangentiality in speech, but responds to structuring in interview. May have to resort to gesture, or mime to communicate.	Lack of coherence, unintelligible speech, significant difficulty following line of thought. Loose associations in speech.

Onset date: _____ ***Offset date:*** _____

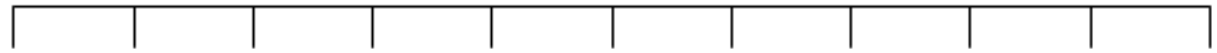
Frequency and Duration

0	1	2	3	4	5	6
Absent	Less than once a month	Once a month to twice a week – **less** than one hour per occasion	Once a month to twice a week – **more** than one hour per occasion **OR** 3 to 6 times a week - **less** than one hour per occasion	3 to 6 times a week - **more** than an hour per occasion **OR** daily – **less** than an hour per occ.	Daily – **more** than an hour per occ. **OR** several times a day	Continuous

Pattern of Symptoms

0	1	2
No relation to substance use noted	Occurs in relation to substance use and at other times as well	Noted only in relation to substance use

Level of Distress (In Relation to Symptoms)



0 **100**

Not At All Distressed Extremely Distressed

8: Inclusion Criteria

Intake Criteria Checklist

Group 1: Vulnerability Group

This criterion identifies young people at risk of psychosis due to the combination of a trait risk factor and a significant deterioration in mental state and/or functioning

	YES	NO
• **Family history of psychosis** in first degree relative **OR Schizotypal Personality Disorder** in identified patient	☐	☐
PLUS		
• **30% drop in SOFAS** score from premorbid level, sustained for a month, occurred within past 12 months **OR SOFAS score of 50 or less** for past 12 months or longer	☐	☐
CRITERION MET FOR GROUP 1 – Vulnerability Group	☐	☐

Group 2: Attenuated Psychosis Group

This criterion identifies young people at risk of psychosis due to a subthreshold psychotic syndrome. That is, they have symptoms which do not reach threshold levels for psychosis due to subthreshold intensity (the symptoms are not severe enough) or they have psychotic symptoms but at a subthreshold frequency (the symptoms do not occur often enough).

	YES	NO
2a) Subthreshold intensity:		
• **Global Rating Scale Score of 3-5** on *Unusual Thought Content* subscale, **3-5** on *Non-Bizarre Ideas* subscale, **3-4** on *Perceptual Abnormalities* subscale **and/or 4-5** on *Disorganised Speech* subscales of the CAARMS	☐	☐
PLUS		
• **Frequency Scale Score of 3-6** on *Unusual Thought Content, Non-Bizarre Ideas, Perceptual Abnormalities* **and/or** *Disorganised Speech* subscales of the CAARMS for **at least a week**	☐	☐
2b) Subthreshold frequency:		
• **Global Rating Scale Score of 6** on *Unusual Thought Content*, **6** on Non-Bizarre Ideas, **5-6** on *Perceptual Abnormalities* **and/or 6** on *Disorganised Speech* subscales of the CAARMS		
PLUS		
• **Frequency Scale Score of 3** on *Unusual Thought Content, Non-Bizarre Ideas, Perceptual Abnormalities* **and/or** *Disorganised Speech* subscales of the CAARMS	☐	☐
PLUS (for both categories)		
• **Symptoms present in past year**	☐	☐
PLUS (for both categories)		
• **30% drop in SOFAS** score from premorbid level, sustained for a month, occurred within past 12 months **OR SOFAS score of 50 or less** for past 12 months or longer	☐	☐
CRITERION MET FOR GROUP 2 – Attenuated Psychosis Group	☐	☐

Group 3: BLIPS Group

This criterion identifies young people at risk of psychosis due to a recent history of frank psychotic symptoms that resolved spontaneously (without antipsychotic medication) within one week.

	YES	NO
• **Global Rating Scale Score of 6** on *Unusual Thought Content* subscale, **6** on *Non-Bizarre Ideas*, **5 or 6** on *Perceptual Abnormalities* subscale **and/or 6** on *Disorganised Speech* subscales of the CAARMS	☐	☐
PLUS		
• **Frequency Scale Score of 4-6** on *Unusual Thought Content*, *Non-Bizarre Ideas*, *Perceptual Abnormalities* **and/or** *Disorganised Speech* subscales	☐	☐
PLUS		
• **Each episode of symptoms is present for less than one week** and symptoms spontaneously remit on every occasion.	☐	☐
PLUS		
• **Symptoms occurred during last year**	☐	☐
PLUS		
• **30% drop in SOFAS** score from premorbid level, sustained for a month, occurred within past 12 months **OR SOFAS score of 50 or less** for past 12 months or longer	☐	☐
CRITERION MET FOR GROUP 3 – BLIPS Group	☐	☐

9: Psychosis Threshold /Anti-Psychotic Treatment Threshold

	YES	NO
• **Severity Scale Score of 6** on *Unusual Thought Content* subscale, **6** on *Non-Bizarre Ideas*, **5 or 6** on *Perceptual Abnormalities* subscale **and/or 6** on *Disorganised Speech* subscales of the CAARMS	☐	☐
PLUS		
• **Frequency Scale Score of greater than or equal to 4** on *Unusual Thought Content*, *Non-Bizarre Ideas*, *Perceptual Abnormalities* **and/or** *Disorganised Speech* subscales	☐	☐
PLUS		
• Symptoms present for **longer than one week**	☐	☐
PSYCHOSIS THRESHOLD CRITERION MET	☐	☐

SOCIAL AND OCCUPATIONAL FUNCTIONING ASSESSMENT SCALE (SOFAS)[1]

Consider social and occupational functioning on a continuum from excellent functioning to grossly impaired functioning. Include impairments in functioning due to physical limitations, as well as due to mental impairments. to be counted, impairment must be a direct consequence of mental and physical health problems: the effects of lack of opportunity and other environmental limitations are not to be considered.

Code (Note: use intermediate codes when appropriate e.g., 45, 68, 72). RATING: _____

100 Superior functioning in a wide range of activities
|
91

90 Good functioning in all areas, occupational and socially effective
|
81

80 No more than a slight impairment in social, occupational, or school functioning (e.g.
| infrequent interpersonal conflict, temporarily falling behind in schoolwork).
71

70 Some difficulty in social, occupational or school functioning, but generally functioning
| well, has some meaningful interpersonal relationships
61

60 Moderate difficulty in social, occupational or school functioning (e.g. few friends, conflicts
| with peers, co-workers).
51

50 Serious impairment in social, occupational, or school functioning (e.g., no friends, unable
| to keep a job)
41

40 major impairment in several areas such as work or school, family relations (e.g. depressed
| man avoids friends, neglects family and is unable to work: child frequently beats up
31 younger children, is defiant at home, and is failing school)

30 Inability to function in almost all areas (e.g. stays in bed all say, no job, home or friends)
|
21

20 Occasionally fails to maintain minimal personal hygiene. Unable to function
| independently.
11

[1] **Note:** the rating of overall psychological functioning on a scale of 0-100 was operationalized by Luborsky in the Health-Sickness Rating Scale (Luborsky L: "Clinicians Judgements of Mental Health" *Archives of General Psychiatry* 7: 401-417, 1962). Spitzer and colleagues developed a revision of the Health-Sickness Rating Scale called the Global Assessment Scale (GAS) (Endicott J, Spitzer RL, Fleiss JL et al: "The Global Assessment Scale: A Procedure for Measuring Overall Severity of Psychiatric Disturbance" *Archives of General Psychiatry* 33: 766-771, 1976). The SOFAS is derived from the GAS and its development is described in Goldman HH, Skodol AF, Lave TR: "Revising Axis V for DSM-IV: A Review of Measures of Social Functioning: *American Journal of Psychiatry* 149; 1148-1156, 1992

10 | 1 Persistent inability to maintain minimal personal hygiene. Unable to function without harming self or others without considerable external support (e.g. nursing care and supervision)

0 Inadequate information

2.9 Outcome measure: Revised Green et al Paranoid Thoughts Scale

Date:	D	D	/	M	M	/	Y	Y	Y	Y
Researcher:										
Pt ID:										
Ax Point:	BL			3M			9M			

Worries About Others

Please read each of the statements carefully. They refer to thoughts and feelings you may have had about others over the **last 2 weeks**. Think about the **last 2 weeks** and indicate the extent of these feelings from 0 (Not at all) to 4 (Totally).

(Please do not rate items according to any experiences you may have had under the influence of drugs.)

Part A:

	Not at all		Somewhat		Totally
1. I spent time thinking about friends gossiping about me.	0	1	2	3	4
2. I often heard people referring to me.	0	1	2	3	4
3. I have been upset by friends and colleagues judging me critically.	0	1	2	3	4
4. People definitely laughed at me behind my back.	0	1	2	3	4
5. I have been thinking a lot about people avoiding me.	0	1	2	3	4
6. People have been dropping hints for me.	0	1	2	3	4
7. I believed that certain people were not what they seemed.	0	1	2	3	4
8. People talking about me behind my back upset me.	0	1	2	3	4

Part B:

	Not at all		Somewhat		Totally
1. Certain individuals have had it in for me.	0	1	2	3	4
2. People wanted me to feel threatened, so they stared at me.	0	1	2	3	4
3. I was certain people did things in order to annoy me.	0	1	2	3	4
4. I was convinced there was a conspiracy against me.	0	1	2	3	4

Date:	D	D	/	M	M	/	Y	Y	Y	Y
Researcher:										
Pt ID:										
Ax Point:	BL			3M			9M			

		Not at all		Somewhat		Totally
5.	I was sure someone wanted to hurt me.	0	1	2	3	4
6.	I couldn't stop thinking about people wanting to confuse me.	0	1	2	3	4
7.	I was distressed by being persecuted.	0	1	2	3	4
8.	It was difficult to stop thinking about people wanting to make me feel bad.	0	1	2	3	4
9.	People have been hostile towards me on purpose.	0	1	2	3	4
10.	I was angry that someone wanted to hurt me.	0	1	2	3	4

2.10 Outcome measure: Depression, Anxiety, and Stress Scale

Date:	D	D	/	M	M	/	Y	Y	Y	Y
Researcher:										
Pt ID:										
Ax Point:	BL			3M			9M			

Day to day feelings

Below are some statements about **feelings**.

Please read each statement and circle a number 0, 1, 2, or 3 which indicates how much the statement applied to you **over the past week**. There are no right or wrong answers. Do not spend too much time on each statement.

Q	Statements	Did not apply to me at all	Applied to me to some degree, or some of the time	Applied to me a considerable degree, or a good part of the time	Applied to me very much, or most of the time
1	I found it hard to wind down.	0	1	2	3
2	I was aware of a dryness of my mouth.	0	1	2	3
3	I couldn't seem to experience any positive feeling at all.	0	1	2	3
4	I experienced breathing difficulty (e.g., excessively rapid breathing, breathlessness in the absence of physical exertion).	0	1	2	3
5	I found it difficult to work up the initiative to do things.	0	1	2	3
6	I tended to over-react to situations.	0	1	2	3
7	I experienced trembling (e.g., in the hands).	0	1	2	3
8	I felt that I was using a lot of nervous energy.	0	1	2	3
9	I was worried about situations in which I might panic and make a fool of myself.	0	1	2	3
10	I felt that I had nothing to look forward to.	0	1	2	3
11	I found myself getting agitated.	0	1	2	3
12	I found it difficult to relax.	0	1	2	3
13	I felt downhearted and blue.	0	1	2	3

Date:	D D / M M / Y Y Y Y			
Researcher:				
Pt ID:				
Ax Point:	BL	3M	9M	

Q	Statements	Did not apply to me at all	Applied to me to some degree, or some of the time	Applied to me a considerable degree, or a good part of the time	Applied to me very much, or most of the time
14	I was intolerant or anything that kept me from getting on with what I was doing.	0	1	2	3
15	I felt I was close to panic.	0	1	2	3
16	I was unable to become enthusiastic about anything.	0	1	2	3
17	I felt I wasn't worth much as a person.	0	1	2	3
18	I felt that I was rather touchy.	0	1	2	3
19	I was aware of the action of my heart in the absence of physical exertion (e.g., sense of heart rate increase, heart missing a beat).	0	1	2	3
20	I felt scared without any good reason.	0	1	2	3
21	I felt that life was meaningless.	0	1	2	3

2.11 Referrals made per site, and per service type, per month

Supplementary table: Referrals per site.

Month	Referrals per month per site		
	OHFT	**BHFT**	**Total**
Oct-20	-	6	6
Nov-20	12	0	12
Dec-20	18	0	18
Jan-21	17	1	18
Feb-21	14	2	16
Mar-21	1	3	4
Apr-21	5	0	5
May-21	7	4	11
Jun-21	4	6	10
Jul-21	5	10	15
Aug-21	14	2	16
Sep-21	4	5	9
Oct-21	0	2	2
Nov-21	13	5	18
Dec-21	2	1	3
Total:	116	47	163
Average:	8.3	3.1	10.9

Supplementary table: Referrals per service type (both sites).

Month	Referrals per month per service type				
	EIS	CAMHS	AMHT/CMHT	IAPT	CPE /SPA
Oct-20	6	0	0	0	0
Nov-20	12	0	0	0	0
Dec-20	15	2	1	0	0
Jan-21	14	4	0	0	0
Feb-21	10	5	1	0	0
Mar-21	3	1	0	0	0
Apr-21	5	0	0	0	0
May-21	6	2	3	0	0
Jun-21	4	4	1	0	1
Jul-21	11	1	1	1	1
Aug-21	6	9	0	1	0
Sep-21	2	7	0	0	0
Oct-21	0	0	0	2	0
Nov-21	8	4	2	4	0
Dec-21	2	0	0	1	0
Total:	104	39	9	9	2
Average:	6.5	2.4	0.6	0.6	0.1

Supplementary table: Referrals per service type (OHFT).

Month	Referrals per month per service type		
	EIS	CAMHS	AMHT/CMHT
Oct-20	-	-	-
Nov-20	12	0	0
Dec-20	15	2	1
Jan-21	13	4	0
Feb-21	9	5	0
Mar-21	1	0	0
Apr-21	5	0	0
May-21	5	2	0
Jun-21	3	1	0
Jul-21	4	0	1
Aug-21	5	9	0
Sep-21	2	2	0
Oct-21	0	0	0
Nov-21	8	3	2
Dec-21	2	0	0
Total:	84	28	4
Average:	6.0	2.0	0.3

Supplementary table: Referrals per service type (BHFT).

Month	Referrals per month per service type				
	EIS	CAMHS	AMHT/CMHT	IAPT	CPE /SPA
Oct-20	6	0	0	0	0
Nov-20	0	0	0	0	0
Dec-20	0	0	0	0	0
Jan-21	1	0	0	0	0
Feb-21	1	0	1	0	0
Mar-21	2	1	0	0	0
Apr-21	0	0	0	0	0
May-21	1	0	3	0	1
Jun-21	1	3	1	0	1
Jul-21	1	1	0	1	0
Aug-21	7	0	0	1	0
Sep-21	0	5	0	0	0
Oct-21	0	0	0	2	0
Nov-21	0	1	0	4	0
Dec-21	0	0	0	1	0
Total:	20	11	5	9	2
Average:	1.3	0.7	0.3	0.6	0.1

Note. In October 2020, only BHFT had given permissions to recruit, meaning that the recruitment window did not open in OHFT until November 2020.

2.12 Data completion rates of measures

Supplementary table: Completion of Assessment Measures, by Treatment Group

Data Completeness	Usual care alone (n=19)	SleepWell therapy (n=21)	Overall (N=40)
ISI			
Baseline, n (%)	19 (100.0)	21 (100.0)	40 (100.0)
3 months, n (%)	18 (94.7)	21 (100.0)	39 (97.5)
9 months, n (%)	18 (94.7)	21 (100.0)	39 (97.5)
SLEEP-50 CRD			
Baseline, n (%)	19 (100.0)	21 (100.0)	40 (100.0)
3 months, n (%)	17 (89.5)	19 (90.5)	36 (90.0)
9 months, n (%)	17 (89.5)	21 (100.0)	38 (95.0)
SleepDiary[1]			
Baseline, n (%)	14 (73.7)	15 (71.4)	29 (72.5)
3 months, n (%)	14 (73.7)	12 (57.1)	26 (65.0)
9 months, n (%)	13 (68.4)	13 (61.9)	26 (65.0)
CAARMS Symptom Severity			
Baseline, n (%)	19 (100.0)	21 (100.0)	40 (100.0)
3 months, n (%)	16 (84.2)	19 (90.5)	35 (87.5)
9 months, n (%)	18 (94.7)	20 (95.2)	38 (95.0)
CAARMS At Risk Status			
Baseline, n (%)	19 (100.0)	21 (100.0)	40 (100.0)
3 months, n (%)	16 (84.2)	19 (90.5)	35 (87.5)
9 months, n (%)	18 (94.7)	20 (95.2)	38 (95.0)
R-GPTS-A (Ideas of Reference)			
Baseline, n (%)	19 (100.0)	21 (100.0)	40 (100.0)
3 months, n (%)	17 (89.5)	20 (95.2)	37 (92.5)
9 months, n (%)	18 (94.7)	21 (100.0)	39 (97.5)
R-GPTS-B (Ideas of Persecution)			
Baseline, n (%)	19 (100.0)	21 (100.0)	40 (100.0)
3 months, n (%)	17 (89.5)	20 (95.2)	37 (92.5)
9 months, n (%)	18 (94.7)	21 (100.0)	39 (97.5)
SPEQ-H			
Baseline, n (%)	19 (100.0)	21 (100.0)	40 (100.0)
3 months, n (%)	18 (94.7)	20 (95.2)	38 (95.0)
9 months, n (%)	18 (94.7)	21 (100.0)	39 (97.5)
CEFSA			
Baseline, n (%)	19 (100.0)	21 (100.0)	40 (100.0)
3 months, n (%)	17 (89.5)	19 (90.5)	36 (90.0)
9 months, n (%)	17 (89.5)	21 (100.0)	38 (95.0)

DASS-21 (Depression)			
Baseline, n (%)	19 (100.0)	21 (100.0)	40 (100.0)
3 months, n (%)	17 (89.5)	19 (90.5)	36 (90.0)
9 months, n (%)	16 (84.2)	21 (100.0)	37 (92.5)
DASS-21 (Anxiety)			
Baseline, n (%)	19 (100.0)	21 (100.0)	40 (100.0)
3 months, n (%)	17 (89.5)	19 (90.5)	36 (90.0)
9 months, n (%)	16 (84.2)	21 (100.0)	37 (92.5)
DASS-21 (Stress)			
Baseline, n (%)	19 (100.0)	21 (100.0)	40 (100.0)
3 months, n (%)	17 (89.5)	19 (90.5)	36 (90.0)
9 months, n (%)	16 (84.2)	21 (100.0)	37 (92.5)
CSSRS			
Baseline, n (%)	19 (100.0)	21 (100.0)	40 (100.0)
3 months, n (%)	16 (84.2)	18 (85.7)	34 (85.0)
9 months, n (%)	16 (84.2)	18 (85.7)	34 (85.0)
DWQ			
Baseline, n (%)	19 (100.0)	21 (100.0)	40 (100.0)
3 months, n (%)	17 (89.5)	19 (90.5)	36 (90.0)
9 months, n (%)	17 (89.5)	21 (100.0)	38 (95.0)
BCSS (Positive)			
Baseline, n (%)	19 (100.0)	21 (100.0)	40 (100.0)
3 months, n (%)	17 (89.5)	19 (90.5)	36 (90.0)
9 months, n (%)	17 (89.5)	21 (100.0)	38 (95.0)
BCSS (Negative)			
Baseline, n (%)	19 (100.0)	21 (100.0)	40 (100.0)
3 months, n (%)	17 (89.5)	19 (90.5)	36 (90.0)
9 months, n (%)	17 (89.5)	21 (100.0)	38 (95.0)
Time Budget			
Baseline, n (%)	18 (94.7)	21 (100.0)	39 (97.5)
3 months, n (%)	16 (84.2)	19 (90.5)	35 (87.5)
9 months, n (%)	15 (78.9)	18 (85.7)	33 (82.5)
WSAS			
Baseline, n (%)	19 (100.0)	21 (100.0)	40 (100.0)
3 months, n (%)	17 (89.5)	19 (90.5)	36 (90.0)
9 months, n (%)	17 (89.5)	20 (95.2)	37 (92.5)
O-AS (Avoidance)			
Baseline, n (%)	17 (89.5)	21 (100.0)	38 (95.0)
3 months, n (%)	17 (89.5)	19 (90.5)	36 (90.0)
9 months, n (%)	16 (84.2)	20 (95.2)	36 (90.0)
O-AS (Distress)			
Baseline, n (%)	18 (94.7)	21 (100.0)	39 (97.5)
3 months, n (%)	17 (89.5)	19 (90.5)	36 (90.0)
9 months, n (%)	15 (78.9)	21 (100.0)	36 (90.0)

BMI			
Baseline, n (%)	14 (73.7)	15 (71.4)	29 (72.5)
3 months, n (%)	15 (78.9)	15 (71.4)	30 (75.0)
9 months, n (%)	11 (57.9)	17 (81.0)	28 (70.0)
Mean Daily Step Count			
Baseline, n (%)	16 (84.2)	16 (76.2)	32 (80.0)
3 months, n (%)	11 (57.9)	15 (71.4)	26 (65.0)
9 months, n (%)	13 (68.4)	14 (66.7)	27 (67.5)
BESAA			
Baseline, n (%)	19 (100.0)	21 (100.0)	40 (100.0)
3 months, n (%)	17 (89.5)	18 (85.7)	35 (87.5)
9 months, n (%)	17 (89.5)	21 (100.0)	38 (95.0)
PHQ15			
Baseline, n (%)	19 (100.0)	21 (100.0)	40 (100.0)
3 months, n (%)	17 (89.5)	19 (90.5)	36 (90.0)
9 months, n (%)	17 (89.5)	20 (95.2)	37 (92.5)
All Substance Use items (MAP) completed[2]			
Baseline, n (%)	19 (100.0)	21 (100.0)	40 (100.0)
3 months, n (%)	17 (89.5)	19 (90.5)	36 (90.0)
9 months, n (%)	17 (89.5)	21 (100.0)	38 (95.0)
At least one Substance Use item completed (MAP)[2]			
Baseline, n (%)	19 (100.0)	21 (100.0)	40 (100.0)
3 months, n (%)	17 (89.5)	19 (90.5)	36 (90.0)
9 months, n (%)	17 (89.5)	21 (100.0)	38 (95.0)
QPR			
Baseline, n (%)	19 (100.0)	21 (100.0)	40 (100.0)
3 months, n (%)	17 (89.5)	19 (90.5)	36 (90.0)
9 months, n (%)	17 (89.5)	21 (100.0)	38 (95.0)
ReQoL			
Baseline, n (%)	19 (100.0)	21 (100.0)	40 (100.0)
3 months, n (%)	16 (84.2)	19 (90.5)	35 (87.5)
9 months, n (%)	17 (89.5)	21 (100.0)	38 (95.0)
EQ-5D-5L Index			
Baseline, n (%)	19 (100.0)	21 (100.0)	40 (100.0)
3 months, n (%)	17 (89.5)	19 (90.5)	36 (90.0)
9 months, n (%)	17 (89.5)	21 (100.0)	38 (95.0)
EQ-5D-5L VAS			
Baseline, n (%)	19 (100.0)	21 (100.0)	40 (100.0)
3 months, n (%)	17 (89.5)	19 (90.5)	36 (90.0)
9 months, n (%)	17 (89.5)	21 (100.0)	38 (95.0)
All Service Use items completed[3]			
Baseline, n (%)	19 (100.0)	20 (95.2)	39 (97.5)
3 months, n (%)	15 (78.9)	18 (85.7)	33 (82.5)
9 months, n (%)	16 (84.2)	17 (81.0)	33 (82.5)

At least one Service Use item completed[3]			
Baseline, n (%)	19 (100.0)	21 (100.0)	40 (100.0)
3 months, n (%)	16 (84.2)	18 (85.7)	34 (85.0)
9 months, n (%)	17 (89.5)	19 (90.5)	36 (90.0)
All Medication Use items completed[4]			
Baseline, n (%)	19 (100.0)	20 (95.2)	39 (97.5)
3 months, n (%)	19 (100.0)	21 (100.0)	40 (100.0)
9 months, n (%)	19 (100.0)	21 (100.0)	40 (100.0)
At least one Medication Use item completed[4]			
Baseline, n (%)	19 (100.0)	21 (100.0)	40 (100.0)
3 months, n (%)	19 (100.0)	21 (100.0)	40 (100.0)
9 months, n (%)	19 (100.0)	21 (100.0)	40 (100.0)

Note. [1]Mean sleep duration per night was used as an indicator of data completion for the sleep diary. Participants with less than 3 days completed diary data were considered as missing. [2]Substance use items include: Alcohol used in the last month (yes/no), cannabis used in the last month (yes/no) and other substances used in the last month (yes/no). [3]Service use items include: Psychiatric admission (number of nights), A&E attendance (number of occasions), meetings with psychiatrist (number of meetings), psychological therapy outside of trial (number of sessions) and number of meetings with a GP.

[4]Medication use items include: Prescribed psychotropic (yes/no), prescribed antipsychotic (yes/no), prescribed antidepressant (yes/no), prescribed anxiolytic (yes/no), prescribed mood stabiliser (yes/no), prescribed hypnotic (yes/no), prescribed promethazine (yes/no) and prescribed other psychotropic (yes/no).

[5]Treatment Outcome ranking items include: Importance ranking for sleep, wellbeing, paranoia, voices visions or other experiences, mood, worry, day to day activity, energy, self-confidence, physical health, things feeling strange and physical activity/exercise.

Chapter 3 - Appendices

3.1 Published manuscript: Waite, F., Evans, S., Rebello, A., Sharpe, T., Otaiku, J., Iredale, E., Kabir, T., Černis, E., & Freeman, D. (2025). Sleep disruption and its psychological treatment in young people at risk of psychosis: A peer methods qualitative evaluation. *British Journal of Clinical Psychology*, 65, 746–761. https://doi.org/10.1111/bjc.70002

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ARTICLE

Sleep disruption and its psychological treatment in young people at risk of psychosis: A peer methods qualitative evaluation

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Abstract

Objectives: A recent randomized controlled feasibility trial showed that sleep problems in young people at risk of psychosis can be successfully treated with psychological therapy and that this may bring additional benefits such as reducing depression, anxiety and paranoia. Here we report participants' qualitative experience of sleep problems and therapy.

Design: A peer-methods qualitative study employing reflexive thematic analysis.

Methods: Semi-structured interviews, co-facilitated by peer researchers, were conducted with 16 young patients at risk of psychosis and having sleep problems who participated in the SleepWell Trial (ISRCTN85601537). Ten interviewees had received the 12-week sleep therapy.

Results: Four themes were generated: (1) the challenge to access mental health treatment ('bouncing between services'), (2) sleep problems and mental health difficulties are intertwined ('an obvious link'), (3) flexibility in therapy provision matters ('tailored to me as a person') and (4) improving sleep leads to wider benefits ('fixing the sleep helped everything else'). Participants described a frustrating journey to access mental health treatment, marked by rejection and invalidation, which resulted in hopelessness and often resignation. The interaction between sleep disruption and other mental health difficulties was seen as

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obvious. Treatment for sleep problems was highly valued. The clear focus, therapeutic style and flexible delivery of the treatment was seen to create patient ownership, active engagement and hope. Participants described transformative changes: better sleep, fewer voices and fears and improved mood and confidence. Improving sleep made a difference to everyday life.

Conclusions: Treating sleep problems in people at risk of psychosis is highly valued and often brings rapid and widespread improvements across a range of domains.

KEYWORDS

at risk mental state, CBT, clinical high risk, cognitive therapy, insomnia, intervention, schizophrenia

Practitioner points

- Young patients describe experiencing sleep disturbance as making other mental health problems worse and that this then exacerbates the sleep difficulties.
- Brief, targeted, psychological treatment for sleep problems is highly valued by young patients at high risk of psychosis.
- Improvements in sleep may bring benefits to mental health and other aspects of day-to-day life.

INTRODUCTION

Sleep problems are a contributory causal factor to the occurrence of a range of mental health problems (Freeman et al., 2020), including psychotic experiences (Reeve et al., 2015; Waite et al., 2020). Successfully treating sleep problems brings wider benefits across mental health outcomes (Scott et al., 2021). In those at highest risk of a mental health condition, treating sleep problems may be a plausible preventative strategy.

Sleep problems are common both in patients with persistent psychosis (Freeman et al., 2019) and in young people at high risk for psychosis (Poe et al., 2017; Zanini et al., 2015), with estimates of prevalence in the at risk group of up to 75%. The range of sleep problems in patients with early psychosis is wide (Dondé et al., 2022). There are also high rates of comorbidity (Reeve et al., 2019). In qualitative accounts, patients describe disrupted sleep timing, anxious waking in the night due to nightmares or unusual experiences, and the negative impact on daytime functioning (Waite et al., 2018). Patients are eager for help (Waite et al., 2018). Yet few have received any treatment (Rehman et al., 2017; Stafford et al., 2024).

Sleep problems can be successfully treated with cognitive behavioural therapy (CBT) even in the context of other mental health conditions (Hertenstein et al., 2022). There are potential wider effects on a range of other mental health outcomes (Freeman et al., 2017; Scott et al., 2021). CBT for sleep problems has been successfully adapted for people with diagnosed psychotic conditions such as schizophrenia (Freeman et al., 2015; Sheaves, Freeman, et al., 2018; Sheaves, Isham, et al., 2018). Given the wider benefits of treating sleep problems, it is also plausible that intervening on sleep before the onset of psychosis might be preventative (Bradley et al., 2018; Freeman et al., 2017, 2020). This is a stance that

is consistent both with a network perspective (Borsboom & Cramer, 2013) and a clinical staging model (McGorry et al., 2014) in which common non-specific factors, which are causally connected within dynamic networks of interacting symptoms, may act as early treatment targets to reduce the likelihood of severe mental health problems. This is what we set out to begin to test in the SleepWell trial (Waite et al., 2023).

In our feasibility trial, 40 young patients (aged 14–25 years old) at ultra-high risk of psychosis were randomized to receive our eight-session targeted psychological treatment (SleepWell) in addition to usual care or to continue their usual care (the control condition). Compared to usual care, provision of the sleep therapy led to substantial reductions in sleep problems and wider benefits across mental health outcomes (Waite et al., 2023). The treatment was popular: 95% of patients took up the treatment, and there were high acceptability scores. There were very large effect size improvements in sleep post-treatment (Cohen's $d = 2.7$) which were maintained at the 9-month follow-up ($d = 1.9$). Provision of the sleep therapy was also associated with medium effect size improvements in anxiety, depression and paranoia, with larger effects observed at the later follow-up.

In this study, we used a peer research approach to try to gain an in-depth understanding of the experience of sleep problems and their treatment with the SleepWell therapy. Peer research is designed and conducted by people with relevant lived experiences. Peer methods can be seen as an important shift towards partnership in the research process (Prebeg et al., 2023). Employing peer methods has the potential to facilitate more nuanced and rich data collection and analysis by enhancing rapport (Terry & Cardwell, 2016) and levelling power (Harding et al., 2010). This collaborative approach, including researchers with different perspectives and expertise, including lived experiences, can strengthen the validity and trustworthiness of qualitative methods (Gillard et al., 2010; Sweeney et al., 2013). Reflexive thematic analysis (RTA; Braun & Clarke, 2021) is an interpretative approach to qualitative data analysis that facilitates the identification of themes (recurring concepts or ideas) in the data and explicitly acknowledges and emphasizes the active role of the researcher in the interpretation. This approach complements peer methods and enables a combination of peer and non-peer perspectives. We conducted a peer-methods qualitative study, employing RTA, to explore SleepWell trial participants' experiences of sleep problems and their treatment.

METHODS

Design

The study received ethical approval from the Health Research Authority (HRA/HRCW: IRAS 281235, The SleepWell trial) and NHS South Central—Oxford A Research Ethics Committee (20/SC/0281) as part of the SleepWell trial.

We conducted a peer-methods qualitative study. The study was designed, conducted and analysed in collaboration with people with relevant lived experience. This included three peer researchers from the SleepWell Lived Experience Advisory Panel (LEAP). The SleepWell LEAP is a group of four people with lived experience of sleep problems and psychotic-like experiences. The LEAP was facilitated by the McPin Foundation (www.mcpin.org), a charity that exists to put the lived experience of people with mental health problems at the heart of research. In line with guidance set out by Prebeg et al. (2023), there was a degree of flexibility (i.e. there were different types of involvement opportunities and roles: advisory panel, data collection, data analysis, authorship) and fluidity (i.e. the opportunity and support to facilitate movement between roles: training on data collection and analysis) in the peer methods. There was also an active effort and attention given to the degree to which power was shared within the research team and process (relational empowerment).

Reflexive Thematic Analysis (Braun & Clarke, 2021) was used to analyse the data. This analytic method is used to identify and infer patterns of meaning across a data set. A critical realist approach was taken based on the assumption that any objective reality is observed through the unique lens of the

researcher. Therefore, this method can accommodate combining peer and non-peer researcher perspectives. Criteria to promote credibility in qualitative research were used to inform the design and conduct of the study (Braun & Clarke, 2021; Tong et al., 2007)—for example Table S3.

Research team—Positionality statement

People with lived experience of sleep problems and psychotic-like experiences were involved in all stages of the study. The research team included three peer researchers who have had similar experiences to those being explored and clinical psychologists who developed the sleep therapy. Working with the LEAP, we aimed to use peer knowledge in the design, procedure and presentation of findings.

Participants

Participants had taken part in the SleepWell trial (ISRCTN85601537; Waite et al., 2023). The participants were young people (aged 14–25 years) attending NHS mental health services with sleep problems who are at ultra-high-risk of psychosis (assessed on the Comprehensive Assessment of At Risk Mental States, CAARMS) (Yung et al., 2005). The inclusion and exclusion criteria for the trial are listed in the trial protocol (Waite et al., 2020). The additional criteria for this qualitative study were: willing and able to give informed consent and willing to have the interview audio recorded and for the use of pseudonymized verbatim quotes. Criterion-based purposive sampling was used to maximize variation in participant characteristics including uptake of therapy, age, gender and ethnicity. Participants were invited to take part in the qualitative study after their final follow-up assessment in the trial (9 months after the baseline assessment). We aimed to recruit 16 people who had taken part in the trial: 10 who had been offered the therapy and six who had not (i.e. were in the treatment as usual only control group). Seventeen people were invited to participate, one declined, 16 consented. Written informed consent, including consent to the use of pseudonymized quotes, was obtained from all participants. Participants were reimbursed for their time.

The intervention

The SleepWell therapy is a brief psychological intervention designed for young people (14–25 years) and targets three mechanisms that help to regulate sleep: circadian rhythm, sleep pressure and hyperarousal. To address circadian alignment (the timing of sleep) we re-align sleep–wake cycles with the natural night-day cycle, using light as the key zeitgeber (time cue). We also use morning routines, daily activity timepoints (i.e., a specific activity at a set time), social connection and mealtimes to support circadian entrainment. Given the common shift in adolescence to a delayed-phase circadian pattern, additional emphasis was put on establishing a consistent sleep window (the ideal time period the person would like to be asleep) and then adjusting the timing of this window to align with the young person's ideal sleep time. To address sleep pressure (the propensity or need for sleep) we promote daytime activity, including the use of fitness trackers. To address hyperarousal, the key strategy is stimulus control, in which patients learn to re-associate bed with sleep. We also use strategies to reduce worry and promote night-time relaxation.

The SleepWell intervention is manualized in a modular format: modules can be selected by patients on the basis of individual need, enabling the intervention to be personalized. The format and manuals were developed in collaboration with the LEAP. Measurement of the sleep problem is taken in every session in order to track progress and retain focus. The treatment was informed by standard CBT sleep protocols (Espie, 2006; Harvey, 2002) and protocols for treating sleep disruption in patients with psychosis (Sheaves, Isham, et al., 2018; Waite, Myers, et al., 2016) with specific adaptations for young

patients at high risk of psychosis, such as addressing psychotic experiences or external stressors (e.g., living independently for the first time or taking exams) that affect sleep and navigating environmental constraints (e.g. shared accommodation with siblings or at university).

The intervention was delivered on an individual basis, in approximately eight 1-h sessions over a 12-week period by a clinical psychologist. Contact between sessions, such as brief telephone calls, text messages or email, was provided to promote the implementation of treatment techniques. Treatment sessions were conducted at the patient's home, at an NHS clinic, or via videocall.

Interview guide

The semi-structured interview guide (see Data S1) was developed with reference to existing literature, guidelines for good practice and in collaboration with the LEAP. It was further refined following pilot interviews with the LEAP. There were three main topics: the participants' experiences of sleep problems; any changes in sleep over the period of trial participation; the experience of taking part in the study and, if applicable, the experience of the sleep therapy. Following guidance from the LEAP, the interview guide was provided to participants before the interview. During the interview, it was used flexibly to focus on the participants' narratives and allow for the exploration of new ideas. Tailored prompts were used to elicit further detail, clarify points, and refocus if needed. The participants' own language was used whenever possible. All four interviewers had received training in interview methods, and each practised the interview in a series of pilots.

Interview process

Interviews were conducted remotely (in line with COVID-19 restrictions) between February 2022 and January 2023. Each interview was facilitated by one peer researcher (AR = 9, SE = 7) and one clinical psychologist researcher (EC = 4, FW = 12). At the start of the interview, the researcher and peer researcher introduced themselves, their expertise and relevant experience. After this, the peer researcher chose when, how and what to share with the participant about their potentially related experiences. This differed between interviews. For six participants, the clinical researcher facilitating the interview delivered the sleep therapy. The peer researchers were not known to any participant. Interviews were conducted in a single session; the duration was between 17 and 68 min (mean = 42 min, SD = 17 min). Brief field notes were taken. Interviews were audio-recorded, transcribed verbatim and deidentified.

Analysis

The six-phase process outlined by Braun and Clarke (2006, 2021) was followed. This included (1) familiarization with the data; (2) generating initial codes—both semantic and latent; (3) generating themes; (4) reviewing potential themes for coherence, meaning and robustness; (5) defining and naming themes and (6) producing the report. Throughout the analysis, specific consideration was given and efforts made to incorporate the range of ways people communicate and articulate themselves during qualitative research (Gupta et al., 2024).

The analysis was completed by multiple coders, all trained in data analysis, including two peer researchers (SE and TS). This was undertaken in a collaborative, reflexive approach with the aim of achieving richer interpretations of meaning, rather than seeking consensus. The analysis was an iterative process with themes discussed with the LEAP and co-authors to consider the most appropriate way to convey the participants' experiences. For example, setting the context of the sleep therapy within the challenging journey to access support was important to the LEAP and is therefore presented as the first theme to provide the reader with this perspective.

398 references were coded. These initial codes were organized into three themes in which common ideas were clustered. The themes were reviewed, reconceptualized and re-labelled to produce the final four themes and three subthemes reported.

Reflexivity and credibility

Prior to data collection, bracketing interviews were conducted to help understand the positionality of the team. The interviewers each maintained a reflexive log throughout the data collection process and had a brief period of joint reflection after each interview to note key learning, draw on the two perspectives and identify any oversights. The construction and interpretation of the coding and themes were discussed and refined with the LEAP and co-authors to invite different perspectives.

RESULTS

Contextualizing the findings

Sixteen people took part. The average age was 18 years old (SD = 2, range 15–22). Eight participants identified as male, seven as femaleand one as other. Most participants were White ($n = 13$), two participants were Asian and one was mixed heritage. Ten participants had received the SleepWell intervention (expected to be delivered in around 8 sessions, with a treatment dose defined as at least four sessions). The mean number of sessions attended was 8.7 (SD = 1.9, range 6–12). All participants had experienced sleep problems. Assessed using the Insomnia Severity Index (ISI) the mean score for all 16 participants at the start of their participation in the trial was in the moderate insomnia range (mean = 17.8, SD = 1.9, range 11–23). For the 10 participants who received the intervention, the mean baseline score was 18.8 (SD = 3.16, range 12–23). At the 9-month follow-up assessment (conducted approximately 6 weeks before the interview), the mean score for the 10 participants who had received therapy was below the clinical cutoff for insomnia on the ISI (mean = 6.5, SD = 5.4, 0–17). For the six participants who did not receive the intervention, the mean score on the ISI was 16.1 (SD = 3.43, range 11–21) at baseline and 11.8 (SD = 6.6, range 6–20) at the 9-month follow-up assessment. The participant characteristics in this qualitative study, including changes to sleep problems post-treatment, are consistent with those seen in the main trial across the whole patient group (see the trial outcome report; Waite et al., 2023).

Overview

Four themes were generated: (1) The challenge to access mental health treatment ('bouncing between services'), (2) sleep problems and mental health difficulties are intertwined ('an obvious link'), (3) flexibility in therapy provision matters ('tailored to me as a person') and (4) improving sleep leads to wider benefits ('fixing the sleep helped everything else'). Participants described being overlooked and finding it hard to obtain help—for sleep problems as well as other mental health difficulties. This left patients with a sense of isolation, frustration and hopelessness. Participants described being engulfed in a loop of co-occurring sleep disruption and mental health struggles. For those who received the SleepWell intervention, flexibility in the delivery of the treatment enabled participants to actively and effortfully, make progress and take ownership of the changes and the process. There were many benefits beyond better sleep: fewer voices and fears, improved confidence, reduced suicidal thoughts, greater connection with others, attendance at work and college and engagement with everyday life. Additional illustrative quotes are provided in Table S1. The pattern of participant contribution to the themes is shown in Table S2.

Theme 1: The challenge to access mental health treatment: 'Bouncing between services'

Participants described the repeated challenges of accessing help—for sleep problems as well as other mental health difficulties: 'Obviously, people like me, obviously have gone through the cracks, a lot' (P3). They described being overlooked and finding it hard to obtain help. The language participants used was striking: 'laid off' (P6), 'abandoned' (P14), 'ignored' (P11) and 'didn't want me' (P3). There was a clear sense of rejection and frustration:

> Yeah, so uh, when I went into services, they kind of just, swiped me under the rug and said 'You know look, we deal with people who are upset or anxious or, kind of this' and they literally said to me 'You're too much of a problem for us with all of the stuff that you're doing to yourself and all the stuff that you're going through so what we're going to do is, we are going to treat it nowhere near as seriously as it should've been' uhm, and you know for me back then, it kind of hit a bit.'
>
> (P6)

Here P6 describes their experience of being ignored, invalidated and uncontained as they sought help from mental health services. There is repetition throughout the interview of key phrases, for example, 'I'm gonna be honest, they weren't very good with me. They kind of, they kind of laid me off and said I was too much of a problem for them to deal with'. As with many participants, this knocked the participants' confidence in services and in themselves—making it harder to continue the journey to accessing help.

These challenges left patients with a sense of isolation and resignation at the start of therapy, rather than hope or expectation. With participants using phrases such as: 'nothing to lose' (P9), 'worth a shot' (P11), 'may as well' (P13), 'this could be a big waste of time' (P3) and 'try anything' (P16).

The LEAP flagged the potential longer-term consequences of not intervening at this key time of mental health deterioration which often occurs during an important developmental life stage. They highlighted the potential benefit of a brief sleep intervention: 'it could make all the difference for those on the edge' and identified opportunities to embed this approach within the treatment pathway between primary and secondary mental health services. This suggestion was consistent with participant accounts in which the sleep treatment was considered a first step, a route to build trust and confidence in services.

Theme 2: Sleep problems and mental health difficulties are intertwined: 'An obvious link'

Participants described the interaction between sleep disruption and mental health difficulties as 'obvious' (P11). Noting with confidence, for example, '100% definitely, definitely, definitely' (P6), that sleep problems, anxiety, depression and psychotic-like experiences were 'intertwined' (P10). The consequences of the spiralling sleep problems and other mental health difficulties were significant: knocking participants' confidence and energy to engage in everyday life, with the LEAP members noting how this often led to isolation, which bought further negative impacts on mental health.

Further to this, participants spoke of the complexity of the sleep disruption itself. Sleep was unpredictable. Sometimes there was too much sleep, sometimes too little and at other times no sleep at all:

> So, in the day, I was just so overwhelmed and anxious by everything, that all I wanted to do was just sleep. But then, sometimes, it would be the opposite. I would be so anxious and worked up that I just can't sleep at all, or I will go to sleep and wake up anxious. Go back

> to sleep, wake up anxious and in a cycle. So, it's not always that I can't sleep but sometimes I think I just want to sleep all the time if I'm particularly anxious, which then, I guess, if I'm sleeping in the day because I'm anxious, then at night you can't sleep because I've slept all day.
>
> (P13)

Sub-theme: Bidirectional interaction between sleep problems and psychotic experiences

A bidirectional relationship was described between psychotic experiences and sleep problems: sleep disruption could both cause voices and fears and result from those psychotic experiences:

> So, if I hadn't slept well, I would end up hearing things a bit more, end up seeing things a bit more and it ended up just really, being worse off without sleep. I think it's something to do with the fact … like I said before, your brain gets overworked, and it starts to like … in terms of computer terms, it starts to malfunction, and it would start to, like, deteriorate a little bit. Then when you sleep, it starts to repair itself. It's like fixing a computer with viruses in it. When it shuts down and it sleeps, it works … it starts to work very well the next day. And I think of the brain like that, as in it's like a computer. As in, it has to shut down, reboot and then it can start doing its daily process.
>
> (P10)

> It was definitely the shadowy figures and those voices that got in the way of sleep, because it just made me anxious. So, I stayed awake for a long time, just so I could calm down. I used to go on games and distract myself instead of having to look at myself. It was tiring. I had like low confidence, low mood and low self-esteem, and during the day I was tired, and it meant I couldn't function properly.
>
> (P9)

For those participants who described being wary and suspicious of others, disrupted sleep made it even harder to trust: 'I'm exhausted maybe I don't want to see any good in someone, so that will make me less likely to trust them'. (P16) and these concerns often played on their mind at night, making it harder to sleep.

For many participants, the interplay of sleep disruption and mental health difficulties was experienced as overwhelming and inescapable. With the interaction described as 'leading me down a hole' (P6), a 'downward spiral' (P16), a 'negative loop' (P6, P9) or 'cycle' (P13) that 'engulfed' (P8) and 'trapped' (P14) participants. The LEAP members reflected how this was consistent with their experiences, as one member put it: 'both the spiral down and recovery can be defined by how you are sleeping'.

Theme 3: Flexibility in therapy delivery and provision matters: 'Tailored to me as a person'

Throughout the participant accounts, the importance of personalization was clear. The specific style of the therapy—characterized by a collaborative, focused, tailored approach—allowed patients to feel heard, validated and empowered to take action and then create a sense of self-ownership of the progress made. Two subthemes are reported that highlight the dynamic interaction between (a) the therapy style, content and deliverer and (b) the active, effortful engagement by the patient.

Sub-theme: Flexibility and rhetoric matter

As reported in Theme 2, participants reported many interacting difficulties that felt overwhelming and unstoppable. In contrast, the therapy had a clear target: improving sleep. This provided focus amidst complexity. The clear aims of the therapy were reflected in the name of the approach, 'SleepWell'. The 'straightforward and transparent' (P8) language helped foster trust. The rhetoric, as termed by the LEAP, of the approach was important for promoting hope, and an understanding of what was expected in this active approach: 'Not talking about stuff, actually doing stuff'. (P1).

Choice, tailoring and personalization were seen as embedded in the approach, and were highly valued. The selection and application of techniques was experienced as individualized: 'it was very tailored to me as a person' (P6). With further recognition that it was personalized for all: 'I genuinely felt like every single person that was a part of this was cared for and thought of and every single case had been adapted to fit that person'. (P14). Yet at times personalization required contrasting styles of treatment delivery. For example, one participant noted that for neurodivergent participants, flexibility meant consistency of sessions and reducing the social demands of the sessions: 'Just about flexibility around a person's different issues, like disabilities or mental illness and stuff. Like, if they have Autism, maybe slow down and let the person think more, rather than being quick … it was difficult for people like me, how to react and how to plan in advance for sessions. … but I think it's good because being active in therapy [it] helps you talk better and let things out' (P9). Therefore, there was choice in the practicalities of sessions, for example, the location, modality (online or in person, remaining within the therapy room or taking a walk during the session), timing and use of materials.

Accessible explanations of the techniques and tailored rationales for their use boosted uptake, for example: 'I found it quite easy to follow. They kind of adapted to my situation, they were very good at that. So, most of the tasks was easy to complete'. (P16). There was a spirit of curiosity and experimentation with the therapy techniques—working collaboratively to discover how a strategy might work best for the individual. Prompts and communication between sessions supported people to try out the techniques: 'they were good with communication, with like emails and text messages to help remind me, so they definitely helped with the reminders of things' (P16). Regular measurement of key outcomes—shared using summary graphs in sessions—provided a 'massive eye opener' (P14). Individuals often described the powerful gains made from specific techniques and shared their understanding of how they might work, for example the wind-down routine was described as: 'having that time to cool down gave my brain a bit of quietness to fully chill out'. (P8). The focus, language and tailored techniques were provided in the context of a therapeutic stance in which participants described feeling heard, understood, remembered and therefore cared for

> Remembering about the people you're talking to definitely made me feel more comfortable because I felt listened to and acknowledged. And for me, the ability to see progress was great. Not just in myself but see it on paper; in graphs and reports that had been built up over the many weeks. To see that result was very, very positive for me to physically look in front of me and go, "cool, here is the actual black and white of how I felt and then this is now". That was really positive. And having the ability to work on it yourself and fill out things, your own personal experience. And then work on that in sessions was great.
>
> (P8)

This extract reflects the specific features of the style, content and delivery of the therapy which were important to participants. These features helped the person to make successful progress and learn skills that could be applied over the longer term. For some, the end of therapy was experienced as abrupt, it 'suddenly stopped' (P9), for others, it 'gradually fizzled out' (P1). Some participants described a sense of loss following a meaningful therapeutic connection and long fought for support. Sometimes it was hard to sustain change after the regular sessions finished: 'so I started to slip up' (P9). Others noted a mix—both satisfaction and nerves at the end of therapy—reflecting the important dynamic of collaboration

in therapy and independently driving and owning progress: 'so I think ending it was … it was nice to know that there had been an end point that had reached, and a result was there, but still a little bit anxious to be on my own with it and not have that person to, like, talk to and discuss about the issues, I suppose.' (P8).

Sub-theme: Active engagement and ownership: Making the most of therapy

Participants described their active effortful approach to the therapy with a sense of ownership: 'I did the hard work' (P3), 'I put the effort in' (P6). Participants were eager to prepare, learn and make the most of the sessions. The therapy materials facilitated a process of discovery—gaining new knowledge and insights. There was an impressive level of detail in the description of specific techniques. One participant described using their new expertise to support their friends to also achieve better sleep. The refreshing, practical, interesting therapy was hard work, yet enjoyable. In the extract below the participant describes how they became increasingly self-reliant as they now had the necessary skills and knowledge to improve their sleep and wider day-to-day life:

> I don't know how to explain it … it was nice to be able to rely on myself to do the routines and everything else. So yeah, it was just very nice to be able to rely on myself instead of everybody else to tell me how to do it. It was relieving that I now had the solution to my problem.
>
> (P11)

Despite the challenging journey to access help and the sense of resignation described in Theme 1, participants became actively committed and engaged in the therapy, finding a 'willingness and wantingness to do it'. (P16) as they became self-reliant and able to successfully apply their learning over the longer term, as it became 'just quite normal now' (P7).

The flexibility, rhetoric and individualization of the therapeutic approach was highly valued by all participants in the study. There were also clear descriptions from interviewees who did not receive the therapy of similar helpful features of how the trial was conducted, such as the choice and options that were actively provided throughout the consent, randomization and assessment procedures.

Theme 4: Improving sleep leads to wider benefits; 'Fixing the sleep helped everything else'

The final theme reflects the meaningful changes participants described as a result of the intervention and the resulting improvement in sleep. This included both the scale of the change, often described as life-changing, and the breadth of the 'knock on benefits' (P6, P8), all of which were said to be noticeable to others.

> One of the things that was rough before was sleep and I think that's sort of had a knock-on effect with sort of everything else to do with my mental health. But the sleep, since being in the trial, has improved drastically and it's sort of, again, I've said it had a knock-on, in a positive way to sort of stabilise everything.
>
> (P8)

Participants used similar evocative phrases when describing the scale of the changes, such as 'transformative' (P3, P14), 'massive difference' (P16) and 'it changed my life' (P2, P10 and P14). Participants particularly noted their surprise at the amount of change achieved in such a short time frame, and when taking a specific focus on one of the many challenges, they were facing: sleep

disruption. The sense of transformation was often linked to the wide range of benefits that participants had noted:

> it's just been a snowball effect of taking more things in and being able to step back a bit more and that's what the therapy has really done for me. It's really allowed me to look at things a lot more, the way I dress, the way I hold myself, the way I act around certain people, the way I interact with people I don't know. People with authority, people above me at work, people-- everybody, everybody and everything I now can sort of see-- I can take a second and look and think before acting. I now feel like everything I do with purpose. And I have the therapy to thank for that, that is sort of unlocked that ability for me. And I really do think it is just patience. That's what it's unlocked for me.
>
> (P14)

In this extract from P14, wider changes beyond improving sleep were described as a 'snowball effect'—reflecting the sense of momentum and ever-growing impact. For this participant, despite the specific focus on improving sleep, the therapy helped change their perception of themselves and their abilities, giving confidence in their capacity to handle situations. This potential was within the participant but hard for them to access, and the brief therapy helped them to 'unlock' patience, perspective and purpose.

The most commonly described benefits were better sleep, fewer voices and fears and re-engagement with everyday life, for example: 'seeing things and hearing things has pretty much disappeared. I'm gonna be honest. … Sleep and stress could always cause this stuff but it just started filtering away and of course the less it happens the less you realise that it happens, um, and its been so long since I've had any like noticeable episodes I guess um, that is just, its just kind of gone' (P6); 'I think sleeping has improved my mood, I wake up happier and I think that sleeping better and being able to sleep faster in the, at night has lowered, you know, my voices at night' (P15). Sleep disruption was 'fixed' (P15), and the benefits were tangible. Participants spoke of how anxiety and low mood improved, as well as a new-found level of confidence which allowed them to do things that previously felt out of reach, for example: 'Yeah, it helped me boost my confidence so I could do more things like go to the shops, go to other places which I wouldn't normally go. Because normally I wouldn't sit on a bus or sit on a train on my own because I'd feel scared and I wouldn't do those things but over time I managed to do both things'. (P9). Improvements in energy levels and greater connection with others were often linked to improvements in daytime activity, as people began to re-engage in work, college and the activities that matter to them. There were other wider improvements such as being able to think clearly, less irritability, fewer suicidal thoughts, fewer appearance-related concerns and better physical health. For the wider benefits participants described potential mechanistic routes to explain the pattern of change: noting that improved energy allowed re-engagement in activity, waking refreshed protected against low mood, thinking more clearly allowed more problem solving, and better sleep not only reduced stress in itself but helped give flexibility, patience and confidence to cope in stressful moments. For some participants, there were fewer changes, for others, the changes were hard to sustain. Overall participants described greater ease, energy and engagement in life.

DISCUSSION

In this peer methods qualitative study, we set out to understand the experience of sleep disruption and its treatment in young people at risk of psychosis. Participants were eager for help to improve sleep and mental health, despite a challenging journey to access support. Participants spoke of an obvious cycle of sleep problems and other mental health difficulties, including psychotic experiences, exacerbating each other. Treatment for sleep problems was highly valued. Consistent with the outcomes of the trial, the participants described rapid and wide-ranging benefits that persisted over time. These results support

the assertion that treating sleep problems can bring quick mental health benefits. Whether intervening on sleep can have more preventative mental health benefits for young people at risk of psychosis will be looked at within the new large multi-centre Sleeping Better trial (ISRCTN71800376).

There was further consistency with the quantitative findings (Waite et al., 2023): the treatment was popular, there were large changes in sleep, and participants described improvements in anxiety, depression and psychotic experiences. The transformative benefits described by several of the participants in our study are consistent with the outcomes of a series of trials across the spectrum of severity of psychosis, all of which demonstrate large effect size improvements in sleep, very high uptake of therapy, and indications of the potential wider mental health benefits (Freeman et al., 2015, 2017; Sheaves, Freeman, et al., 2018).

The findings in this study are also consistent with other patient accounts of sleep disruption in the context of psychotic experiences, including: the complexity of sleep problems and range of presentations (Waite et al., 2018), the wide impact of sleep problems (Chiu et al., 2016; Faulkner & Bee, 2017), and the value and benefits of treatments for sleep disturbance (Waite et al., 2018; Waite, Evans, et al., 2016). Both the sense of hopelessness at the outset of treatment and the eagerness for help is common in accounts from patients with persistent psychotic experiences (Chiu et al., 2016; Faulkner & Bee, 2017; Waite, Evans, et al., 2016) and those at risk of psychosis (Waite et al., 2018), including an openness to the use of technology in treatment (Taylor et al., 2022), such as wearable devices (Griffiths et al., 2021). To our knowledge, this is the first peer methods study to explore first person accounts of sleep disruption and its treatment in young patients at risk of psychosis. The peer researchers gave a particular opportunity to discuss experiences of therapy, as well as difficulties with sleep and other mental health problems, and bought this specific lens to the analysis. These findings provide an insight into the dynamic process of therapy in which the specific style, content and alliance enabled participants to take both an active role and degree of ownership of the resulting improvements. The importance of personalization and tailoring was clear—with further work to adapt for neurodivergent participants required. Personalization may be particularly important in future implementation, especially given the complexity of the presentation of sleep problems in this group (Dondé et al., 2022; Freeman & Waite, 2025; Harvey, 2022; Reeve et al., 2019). There are promising initiatives to embed sleep interventions into youth mental health services (Rollinson et al., 2024), and potential opportunities within the NHS community transformation initiative. Given the challenges and evocative language described in the first theme, as well as the potential window of opportunity for prevention, it is imperative that any intervention in this high-risk group is accessible.

There are a number of limitations. Firstly, the research was conducted in a single centre in the United Kingdom and the participants will not be representative of all young patients attempting to access services. Notably, there were no specific clinical services for young people at risk of psychosis at the recruiting sites; therefore, usual care was limited. There was limited ethnic and gender diversity in the participants interviewed. Differential access to mental health services as well as treatment outcomes for psychosis are reported in young patients from minoritized backgrounds (Chui et al., 2021; Coelho et al., 2022; Morgan et al., 2017), especially Black African and Black Caribbean patients. Therefore, understanding the potential barriers faced by underrepresented groups will be important in both future evaluations of the therapy and implementation. The sampling method was intended to maximize variation, including with regard to therapy uptake; however, we only interviewed people who had completed therapy, which is largely a reflection on the uptake of the therapy in the trial (only one person did not receive a treatment dose). There may be specific challenges for those participants who choose not to complete therapy, which will be more likely to be seen in larger trials. Similarly, there were extremely few people in the trial who did not improve their sleep from the intervention, and their perspective will likely be different and was not captured in the current report. Therefore, one notable omission from the data set is detailed insight into the potential challenges and drawbacks of therapy. This is potentially due to sampling bias—as outlined above. It may also be due to difficulties in data collection. Peer methods were used to try to balance power and invite rich accounts. However, a clinical psychologist researcher was also present. For a subgroup of participants ($n = 6$), this was the therapist they had worked with in the trial intervention.

In recognition of this limitation in the data, a LEAP meeting was held specifically to consider the potential downsides and drawbacks of therapy. The LEAP highlighted the investment of time and resources and the potential emotional demands of a psychological intervention. Future work is needed to investigate potential adverse effects and demands of psychological interventions in young people at risk of psychosis. Working within a peer methods framework, we deliberately sought out different perspectives, experiences and expertise throughout the data collection and analysis. However, we recognize the persistence of an ableist bias within our methods, common in qualitative research with patients with psychosis (Gupta et al., 2024), reflected in the use of articulate illustrative quotes within the report. In line with recent recommendations (Gupta et al., 2024), we want to find routes to improve inclusivity with regard to neurodiversity and the range of ways people articulate and communicate. It would also be valuable to seek further feedback from the peer-researchers regarding their experience of actively engaging as partners in the research process. In other peer research with young people at ultra-high risk of psychosis, the role has been highly valued (Trimmel et al., 2024). Understanding the peer experience in terms of flexibility, fluidity and relational empowerment (Prebeg et al., 2023) could inform future peer-methods research. We also note that the therapy was conducted during the COVID-19 pandemic. The context of restrictions and disruption, within services and day-to-day life, may have affected the experience of sleep disruption, mental health difficulties and the therapy.

Young people at risk of psychosis face multiple mental health problems. Given sleep disruption is a contributory causal factor in the occurrence of mental health difficulties, treating sleep problems may be a valuable starting point for intervention—it provides focus amidst complexity, is quickly tractable and may bring wider benefits to both the short and longer-term trajectory. The next step is a definitive trial, with embedded mediation and moderation tests, to determine the wider effects. The Sleeping Better trial (ISRCTN71800376) is now underway.

AUTHOR CONTRIBUTIONS

FW was the chief investigator, conceived of the study, had full access to all the data and wrote the first draft of the manuscript. FW and DF led the trial design and treatment design. TK led lived experience involvement. The SleepWell Lived Experience Advisory Group (SE, AR, TS and JO) provided lived experience expertise. EI recruited participants. SE, AR, EČ and FW conducted the interviews. SE, TS and FW led the analysis. All authors contributed to critical review and editing of the manuscript.

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CONFLICT OF INTEREST STATEMENT

All authors declare no competing interests.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

3.2 Invitation and outline of the interview co-facilitator role

SleepWell

Qualitative Research Co-Facilitator Role

After the SleepWell meeting in July, we thought about how participants might answer questions differently depending on what the questions are, but also ***who*** asks them and ***how*** they are asked.

When carrying out the interviews, we want participants to feel comfortable to share their experiences of taking part in SleepWell. This can be easier when interviews are carried out by someone who has had similar experiences to them. **That is why we would like to have the interviews run jointly ('co-facilitated') by Emma or Felicity and one of our YPAG members.** A co-facilitator draws on both their research knowledge *and* their lived experience when they carry out interviews.

'Co-facilitation' is an approach used more and more in mental health research because it is clear that it helps participants feel at ease, and leads to really interesting new perspectives and information – which makes the whole study more valuable.

This document

This document outlines the role of the SleepWell Qualitative Research Co-Facilitator. It also includes some points that you may find helpful to discuss with friends/family, Oli and McPin, and/or Felicity and Emma when deciding if this role might be of interest to you.

Anyone taking up this role will be supported as fully as possible by Felicity, Emma, and the rest of the SleepWell team.

If you have any questions about anything in this document, please contact us: emma.cernis@psych.ox.ac.uk or felicity.waite@sjc.ox.ac.uk

The role of the co-facilitator

The co-facilitator will join Emma or Felicity for **approximately 8 interviews**. The aim of the interviews is to learn from SleepWell participants who have finished the trial: we will be asking how they experienced the research and therapy during their participation. Interviews will last for about **1 hour** and will happen approximately **once per month** between **September 2021 and May 2022**. They will take place **online or somewhere local to the participant**.

Training in how to carry out the interviews will be provided by Emma and Felicity, and you will be supported by Emma, Felicity, and the rest of the SleepWell team throughout.

Drawing on lived experience expertise

If you take part in the interviews, you would need to feel confident and comfortable with letting the participant know that you have had similar experiences to them. We will discuss together before the interview how you would like to explain this to participants, and how much

information you would feel comfortable sharing. You will never be asked to share something that you do not want to with the participants (or with Emma or Felicity)!

Training

We will give you training on what to do in the interview. As you know, we have already developed the interview questions together in our YPAG meetings: in the training we will practice asking them. We will also think about what we will do as a team if something unexpected comes up during the interview appointment.

Training might include role play and other ways of practicing, will take approximately 2 hours. It will likely be online with Emma and Felicity, and possibly with any other co-facilitators, too.

To help with your developing interviewing skills, Emma or Felicity will also check in with you after each interview to see how you found it - and so that we can work together to keep improving how we run the interviews. Once the first couple of interviews are typed up (these are called 'transcripts'), we will also talk through these together.

As above, there will be time in training to think about what you want to share from your lived experience, and to practice this.

Other points

Interviews will be (audio) recorded so we can capture all the information for analysis later. (So the co-facilitator needs to be happy to be recorded). And if taking place online, the interviewers' cameras will need to be on so that we can help participants feel as comfortable as possible talking to us. (So the co-facilitator needs to be happy to have their camera on).

When we start working together, we will create an agreement in advance on what to do if it becomes difficult for you to co-facilitate the interviews (for any reason), and we will make sure that this agreement still suits you by reviewing it regularly. This means it will be helpful for you to keep us updated on how you are finding the role and whether we need to do anything differently to better support you.

What we would NOT expect the co-facilitator to do

1. Arrange interviews – Emma or Felicity will be in charge of booking the appointments, the rooms, and making transport plans for everyone. They will also be in charge of recording the interview and keeping that data safe.

2. Manage risk – There is a chance that participants might discuss sensitive topics, and some of this might require Emma or Felicity to act upon their duty of care to keep everyone safe. We would *not* expect the co-facilitator to have any role in this, and we would make sure that you are supported during and after any interviews where this comes up.

Payments

Payment will be at the same rate per hour as the SleepWell meetings.

3.3 Template peer researcher 'Working Well Together Plan'

Working Well Together Action Plan

Name:
Date:

1. What helps you stay well at work?
2. What can Emma/Felicity do to help you to stay well at work? (e.g. what are your preferences for receiving and giving feedback, how we stay in touch etc.)
3. Are there any situations / topics / etc. that may act as a trigger for you? What can we do to minimise these for you? (e.g. before/after an interview, in the interview location, as a topic of discussion during an interview?)
4. Are there any signs that we may notice if you were beginning to find things difficult?
5. If we notice these signs – what can we do?
6. Is there anything else that you would like to share?

3.4 Interview schedule: Participant copy of interview questions

SleepWell

Experiences of taking part in the SleepWell study

Participant copy of questions

The interviewer(s) will introduce themselves and remind you about the SleepWell trial, tell you how long the interview will be (and let you know about breaks etc.), and will check again that we have your permission to record.

The interviewer will give you a short update on how the study is going at the moment before we begin the interview.

We will then discuss these main topics:

1) **How are things for you at the moment, and your sleep in particular?**

2) **Have there been any changes?**
In your sleep? In other areas? Has anyone else (friends or family, or other significant or important people important in your life) noticed anything has changed?

3) **What was the study like? (How did you find it taking part?)**
e.g. what were the assessments like? What was it like to have 50:50 chance of getting the full therapy? Etc.

3a) What was the impact of the COVID-19 pandemic on your experience of taking part in SleepWell?
e.g. what was it like having remote sessions, or researchers wearing PPE? Etc.

4) ***If you had it:*** **How did you find the therapy?**
e.g. what was most / least helpful? What was it like working with your therapist?

5) **Is there anything that we haven't asked that you feel may have been important to your experience?**
Any suggestions for a future version of the study? Anything else you would like to add?

If there are any comments or opinions you would like to feedback but forget to mention in the interview, or do not feel able to say during the appointment, you can send these to the SleepWell team anonymously using this online comment box:

3.5 Analysis: Extract of preliminary coding

	Excerpt from transcript	**Preliminary coding**
I	I guess I'm kind of wondering what you think was maybe causing your sleep problems before the therapy?	
P	It was definitely the shadowy figures and those voices, because it just made me anxious. So, I stayed awake for a long time, just so I could calm down. I used to go on games and distract myself instead of having to look at myself.	Sleep problems may be caused by visions and associated fear; too afraid to sleep. It took long efforts to calm sufficiently for sleep. Recognition of the need to reduce arousal for sleep – yet the challenge due to heightened fear from visions. Including distraction with gaming. Practical strategies might be useful. Adaptions to stimulus control principles may be needed.
I	Yeah, that sounds really tough at that time.	
P	Yeah.	
I	What was the impact of not sleeping well day-to-day?	
P	It was tiring. I had like low confidence, low mood and low self-esteem, and during the day I was tired, and it meant I couldn't function properly.	There was a major impact of sleep problems – on confidence, mood, functioning. There were many wider effects of sleep disruption.

Note. Account selected with an emphasis on inclusive research practice particularly with regards to neurodiversity and the range of ways people articulate and communicate – see guidance by Gupta et al., 2024.

3.6 Analysis: Example coding structure for individual participant

Theme	**Codes**
Visions make it hard to sleep	Impact on confidence, mood, functioning
	Understanding this unlocked change – actively break cycle
The swinging pendulum: too much and too little sleep	The complexity of sleep problems
	There were many wider effects of sleep disruption.
Life is better when you sleep better	Fewer visions, more relaxed, doing enjoyable activities; easier to think clearly, social connections increased
	Life easier – calming anxiety
	Boost confidence
	Use benefits to build hope
	Empowerment
Make it fit for the individual (adjustments for neurodiversity)	Flexible adaption a key part of the therapy: choice matters
	Anxiety regarding therapeutic alliance fuelled by autism
	Need clear and consistent sessions especially for neurodiverse participants
	Gentle, persistent, engagement
	Getting active in sessions reduces the social demands of session and can help to build trust and the individual to open up. Being more adaptive to build trust.
	Don't hesitate in treatment – get on and make the change, this helps to build/earn trust
Hard to access help	Nothing to lose – no positive expectations of treatment

Note. Account selected with an emphasis on inclusive research practice particularly with regards to neurodiversity and the range of ways people articulate and communicate - see guidance by Gupta et al., 2024.

3.7 Analysis: Example thematic map and coding structure across participants

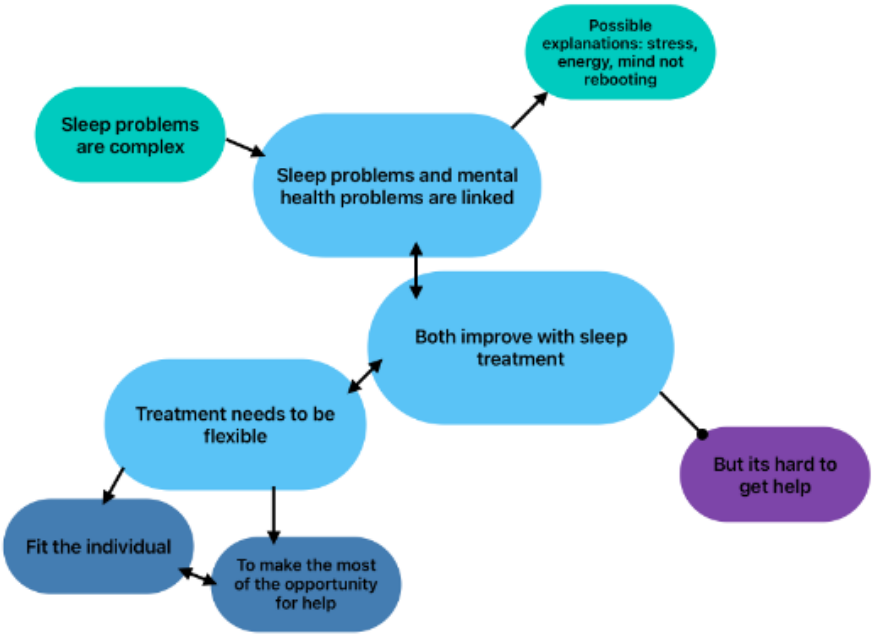

Figure 1. Thematic map discussed in LEAP meeting after analysis with data from 10 participants