Institution: University of Oxford

Unit of Assessment: 4 – Psychology, Psychiatry and Neuroscience

Title of case study: Improving mental health and wellbeing through digital cognitive behavioural therapies for Insomnia and Generalised Anxiety Disorder

Period when the underpinning research was undertaken: 2013-2020

Details of staff conducting the underpinning research from the submitting unit:

Name(s):	Role(s) (e.g. job title):	Period(s) employed by submitting HEI:
Colin Espie	Professor of Sleep Medicine	Feb 2013 – present
Daniel Freeman	Professor of Clinical Psychology	2011 – present
Simon D Kyle	Associate Professor	2015 – present
Annemarie I Luik	Research Fellow	Jun 2015 – Feb 2018
Guy M Goodwin	Professor of Psychiatry	1996 – March 2018
Paul J Harrison	Professor of Psychiatry	1998 – present
Bryony Sheaves	Research Clinical Psychologist	Oct 2013 – Sept 2018

Period when the claimed impact occurred: 1 August 2013 - 31 December 2020

Is this case study continued from a case study submitted in 2014? N

1. Summary of the impact

Research at the University of Oxford has shown that two digital cognitive behaviour therapies (CBTs) 'Sleepio' (targeting insomnia) and 'Daylight' (targeting generalised anxiety disorder) are effective and can be used as scalable interventions with wide ranging effects on mental health, wellbeing and workplace productivity. These digital CBTs have been widely used across the UK since October 2018 to help more than 21,000 people, including NHS and social care staff during the COVID-19 pandemic, improve their sleep, wellbeing and mental health. Since June 2019 and July 2020 respectively, Sleepio and Daylight have been made available through health insurers and occupational health programmes in the US and used by thousands of employees across 42 employers to improve workforce health and productivity.

2. Underpinning research

Chronic insomnia, defined as difficulty sleeping for 3 nights a week for 3 months or more, affects one in ten adults and a significantly greater proportion of those with long-term health conditions. Cognitive Behavioural Therapy (CBT) is recommended as the first-line treatment for insomnia in adults, by helping people to develop coping strategies and change unhelpful thought patterns and behaviours. However, insufficient numbers of trained therapists, intervention costs and perceived stigma limit access to CBT. Digital CBTs (dCBT) overcome such barriers because digital devices are widespread, enabling effective therapy to be accessed discreetly, immediately and at low cost. 'Sleepio' is a fully automated, interactive web-based dCBT to address insomnia that was initially developed by Professor Colin Espie before he moved to the University of Oxford at the start of 2013. Since then, Espie and colleagues in Oxford have further developed the content of Sleepio and have demonstrated its wide-ranging beneficial effects in randomised controlled trials (RCTs).

Generalised anxiety disorder (GAD) is a condition involving excessive anxiety and worry, affecting 5-8% of the population. CBT is the recommended treatment for GAD, but is limited by the same stigma and access challenges as CBT for insomnia. The University of Oxford team conducted the first RCT of Daylight, a new web and mobile dCBT, developed to treat moderate-to-severe symptoms of GAD at scale. To meet this scale of adoption, Both Sleepio and Daylight have been developed for market by Big Health, a company that Espie co-founded.

A. Development of a new insomnia screening tool for inclusion in Sleepio

The Sleep Condition Indicator (SCI) was developed by Espie [1] to address the Sleepio programme's need for a tool that appraised Insomnia Disorder against Diagnostic and Statistical

Manual of Mental Disorders (DSM-5) criteria. Espie led the project to instrument and validate this novel measure on over 200,000 participants with Kyle and Luik in Oxford, together with colleagues in Glasgow, Manchester, London and at Big Health [2]. The SCI was incorporated within Sleepio to measure the need for intervention and to evaluate clinical change in insomnia. The SCI is an accessible 8-question questionnaire, but Espie also developed and published a shorter 2-question version to enable rapid screening for insomnia by GPs in primary care.

B. Evaluation of benefits of Sleepio for mental health, well-being and productivity
Between 2015 - 2017, the University of Oxford team carried out the OASIS (Oxford Access for Students Improving Sleep) trial in a population of 3,755 students at 26 UK universities to investigate whether improving sleep benefitted psychological health [3]. The study randomised students to dCBT for insomnia (Sleepio) or usual practice. The trial demonstrated that Sleepio reduced insomnia, that insomnia reduction mediated changes in mental health symptoms including even severe symptoms and highlighted the need to prioritise improvement in sleep in mental health clinical services. The trial was hosted by the University of Oxford with colleagues from across UK universities participating. It was led by Professor Daniel Freeman with other University of Oxford researchers, including Espie, responsible for the digital therapy programme and contributing to the study conception and design.

Espie and colleagues from the UK, Australia and the US investigated the effect of improving sleep on functional health, psychological well-being and sleep-related quality of life [4]. The trial, hosted by the University of Oxford, randomised 1,711 adult participants with insomnia to dCBT (Sleepio) or traditional sleep hygiene advice. The trial demonstrated the superiority of dCBT over sleep hygiene advice in improving functional health, quality of life and wellbeing outcomes and showed that a reduction in insomnia symptoms mediated these improvements. Follow-up of participants in 2019 showed that treatment gains were sustained at 48 weeks, with analysis indicating that improvements in outcomes were mediated by earlier improvements in insomnia symptoms.

Espie and Luik (with Bostock from Big Health) carried out a trial involving executives at a Fortune 500 company, to evaluate potential benefits of improved sleep to productivity in a workplace environment [5]. A total of 270 self-identified poor sleepers was randomised to dCBT (Sleepio) for insomnia or a waitlist control. Using a validated work productivity and impairment questionnaire, the group showed that participants receiving Sleepio reported a 15% increase in productivity at work as well as improved sleep. The results were maintained at three-month follow-up.

C. Evaluation of benefits of Daylight for Generalised Anxiety Disorder
Espie, Goodwin and colleagues at the University of Oxford conceived and led the foundational RCT of Daylight at the University of Oxford, in partnership with colleagues in London, the US and at Big Health. A total of 256 adults was randomised to either dCBT or a waitlist control. Anxiety symptoms were assessed by the GAD-7 measure; secondary outcomes including worry, depressive symptoms and wellbeing were also measured. Daylight reduced symptoms of anxiety compared with controls at post-intervention (6 weeks) and follow up (10 weeks), and significant improvements were also found for the other measures [6]. The results indicated that Daylight is safe and efficacious for symptoms of anxiety, worry, depression and mental wellbeing compared to waitlist control in individuals with GAD.

3. References to the research (authors in bold employed in Oxford at the time of the research)

1. **Espie CA**, Kyle SD, Hames P, Gardani M, Fleming L and Cape J (2014). The Sleep Condition Indicator: a clinical screening tool to evaluate insomnia disorder. *BMJ Open* 4 DOI:10.1136/bmjopen-2013-004183
2. **Espie CA**, Farias Machado P, Carl JR, **Kyle SD**, Cape J, Siriwardena AN and **Luik AI** (2018). The Sleep Condition Indicator: reference values derived from a sample of 200,000 adults. *Journal of Sleep Research* 27(3). DOI:10.1111/jsr.12643
3. **Freeman D**, **Sheaves B**, **Goodwin GM**, Yu LM, Nickless A, **Harrison PJ**, Emsley R, **Luik AI**, Foster RG, Wadekar V, Hinds C, Gumley A, Jones R, Lightman S, Jones S, Bentall R,

Kinderman P, Rowse G, Brugha T, Blagrove M, Gregory AM, Fleming L, Walklet E, Glazebrook C, Davies EB, Hollis C, Haddock G, John B, Coulson M, Fowler D, Pugh K, Cape J, Moseley P, Brown G, Hughes C, Obonsawin M, Coker S, Watkins E, Schwannauer M, MacMahon K, Siriwardena AN and **Espie CA** (2017). The effects of improving sleep on mental health (OASIS): a randomised controlled trial with mediation analysis. *Lancet Psychiatry* 4(10), 749-758. DOI:10.1016/S2215-0366(17)30328-0

4. **Espie CA**, Emsley R, **Kyle SD**, Gordon C, Drake CL, Siriwardena, AN, Cape J, Ong JC, **Sheaves B**, **Foster R**, **Freeman D**, Costa-Font J, Marsden A and **Luik AI** (2019). Effect of Digital Cognitive Behavioural Therapy for Insomnia on Health, Psychological Well-being, and Sleep-Related Quality of Life: A Randomized Clinical Trial. *JAMA Psychiatry* 76(1): 21-30. DOI:10.1001/jamapsychiatry.2018.2745
5. Bostock S, **Luik AI** and **Espie CA** (2016). Sleep and Productivity Benefits of Digital Cognitive Behavioural Therapy for Insomnia: A Randomized Controlled Trial Conducted in the Workplace Environment. *J Occup Environ Med*. 58(7):683–689. DOI:10.1097/jom.0000000000000778
6. Carl JR, Miller CB, Henry AL, David ML, Stott R, Smits JAJ, Emsley R, Gu J, Shin O, Otto MW, Craske MG, **Saunders KEA**, **Goodwin GM** and **Espie CA** (2020). Efficacy of digital cognitive behavioural therapy for moderate-to-severe symptoms of generalized anxiety disorder: A randomized controlled trial. *Depression and Anxiety*. 37:1168-1178. DOI:10.1002/da.23079

Reference 3 supported by Wellcome Trust Strategic Award to the University of Oxford, 'Sleep and Circadian Neuroscience Institute (SCNi)', GBP4,430,000 (098461/Z/12/Z, Oct 2012 to Sept 2018) with co-investigators including Freeman, Goodwin and Harrison.
References 3,4 and 6 supported by NIHR Oxford Health Biomedical Research Centre and NIHR Oxford Biomedical Research Centre grants.

4. Details of the impact

Chronic insomnia affects people through lack of energy, poor concentration and productivity, increased accident rates, heightened stress and low mood and longer term, increases the risks of diabetes, heart disease, infectious diseases and early mortality. It is a barrier to effective self-care and leads to greater healthcare costs. CBT for insomnia (CBTi) is lastingly effective and is the recommended treatment of first choice for chronic insomnia in European and American guideline documents. Sleepio has a considerable evidence base including the University of Oxford-based trials [3-5], the findings from which have influenced uptake of digital CBTi as an intervention to improve mental health and wellbeing in particular. Two of these trials [3,4] are highlighted in the 2019 consensus statement for evidence-based treatment of insomnia from the British Association for Psychopharmacology as demonstrating a causal relationship between improvements in sleep and improvements in mental health symptoms, wellbeing and quality of life [A]. The considerable evidence base for Sleepio contributes to the statement in this document that digital CBTi has the potential to offer a choice amongst evidence-based alternatives (CBT or drugs) in routine clinical care. Additionally, the University of Oxford studies on students and employees [3,5] are cited in a RAND Europe report reviewing promising workplace wellbeing interventions to aid organisations in developing their workplace wellbeing offer and contribute to Sleepio being given the highest evidence-based rating in the report [B].

Improvements to mental health and wellbeing through uptake of Sleepio

The trials conducted by University of Oxford researchers [3-5] have been cited in evaluations of Sleepio, which have subsequently influenced uptake. For example, the first systematic evaluation by NICE of a digital therapeutic intervention was a MedTech Innovation Briefing (MIB) on Sleepio in November 2017 and summarised evidence 'based on 5 well-designed and well-reported randomised controlled trials' that included the Freeman et. al. [3] and Bostock et. al. [5] trials [C].

The same trials [3,5] were referenced in the successful application, 'Enabling better health and self-care at scale with digital sleep medicine' submitted by Big Health and the Oxford Academic

Health Science Network (AHSN) to Innovate UK for its Digital Health Technology Catalyst competition in 2017. The project aimed to explore different routes to enable immediate access to CBT and was one of only 9 funded from several hundred in total [D]. In this first large-scale NHS rollout of direct access digital medicine, Sleepio was made freely available across the Thames Valley (an adult population of 2,700,000) and individuals were able to access the programme without needing a GP referral or prescription. Launched in October 2018, the project has been adopted in local primary care, by local employers and by the Improving Access to Psychological Therapies (IAPT) programme (a national programme which uses talking therapies to help people overcome depression and anxiety and better manage their mental health). From October 2018 to June 2020, more than 16,000 people completed a Sleepio sleep score test, with 7,078 of these going on to start the personalised CBT programme. There were 3,600 referrals from 19 GP practices over this period and there was positive feedback on the ease of prescribing, integration into GP workflow and reduction of the burden on GPs. In addition, results from nine GP surgeries projected savings of around GBP100 for each Sleepio user over 3 years. A joint report from the Oxford AHSN and Big Health published in August 2020 [E] highlights these benefits.

Big Health partnered with the NHS to provide free access to Sleepio for all NHS and social care staff between April 2020 and December 2020 (3,000,000 individuals) as part of a package of health and wellbeing support for keyworkers during the COVID-19 pandemic [F]. Clinical evidence from the University of Oxford trials [3-5] was important in the decision by the NHS to choose Sleepio and Daylight as two of the four mental health and wellbeing apps made available [G,H(i)]. In England and Scotland, 18,000 sleep tests for Sleepio have been accessed through this provision with 10,000 individuals going on to start the CBT programme (up to the end of November 2020) [H(ii)].

Following the success of the Thames Valley project, five health boards in Scotland covering a population of 1,700,000 approved roll-out of Sleepio in evaluation projects in December 2020 to tackle insomnia and anxiety. The University of Oxford efficacy studies [3,4] and impact of the Thames Valley study were said by the National Advisor for Digital Mental Health for the Scottish Government to be crucial in securing the roll-out [I].

Uptake of Sleepio in the US to improve wellbeing and productivity

Since 2019, there has been a major increase in the uptake of Sleepio in the US where it is being adopted to improve workplace health, wellbeing and productivity. In June 2019, Sleepio announced a landmark partnership with US insurers CVS Health which has 94,000,000 medical benefit members, offering the prospect of mainstream adoption of digital therapeutics for the first time within the US healthcare system [J]. [Text removed for publication]. Uptake of Sleepio in the US has been facilitated by the strong evidence base from University of Oxford research [3,4] and recognition that the product provides a scalable approach to tackling poor sleep amongst the workforce and improving well-being and productivity [L].

Adoption of the SCI as a clinical insomnia tool

Both the 8 and 2-question versions of the SCI have been routinely adopted for use in Sleepio. It is the metric used to assess the benefit of Sleepio and provides a robust tool in place of the sleep diary that individuals previously completed. Users go to the Sleepio website and complete an initial 5-minute sleep score test which includes the SCI. This simple and clinically meaningful entry into Sleepio is believed to have facilitated Sleepio's adoption by individuals, clinical services and workplace referrers, based on numbers who have enrolled in the initial sleep score test: 16,000 and almost 18,000 for the Thames Valley and NHS/social care staff roll-outs respectively.

Recognised as a robust means of measuring sleep, the SCI has also been adopted as a clinical tool for insomnia outside Sleepio. It was promoted for use in primary care by GPs in 2019 via the Red Whale GP CPD update [M], a recognised and reliable source of clinical knowledge and guidance that is sent to ~30,000 of the UK GPs. The update recommends the 2-item questionnaire, leading to the 8-item questionnaire if required, as a short screening tool to use in some chronic disease reviews and cites Espie and colleagues' work [1].

Access to the Daylight intervention through programmes in the UK and the US

The digital therapeutic intervention Daylight, evaluated in the RCT carried out at the University of Oxford [6], has been made freely available alongside Sleepio between April 2020 and December 2020 to support NHS and social care staff during the COVID-19 pandemic [G]. Up to the end of November 2020, almost 9,000 staff in England and Scotland had signed up for Daylight with around 4,600 going on to start the CBT programme [H(ii)]. The roll-out of Daylight in clinical services across 5 health boards in Scotland as part of a national computerised CBT programme, covering 1.7m people, began in December 2020 [I]. Daylight has also been added to the CVS Health formulary in the US making it available to around 2,800,000 individuals there [L].

5. Sources to corroborate the impact

A. Wilson S, Anderson K, Baldwin D, Dijk DJ, Espie A, Espie C, Gingras P, Krystal A, Nutt D, Selsick H and Sharpley A (2019). British Association for Psychopharmacology consensus statement on evidence-based treatment of insomnia, parasomnias and circadian rhythm disorders: An update. *J Psychopharmacol*. 33(8):923–947 DOI:10.1177/0269881119855343

B. Whitmore et al. 2018 Promising practices for health and wellbeing at work: A review of the evidence landscape. RAND Corporation. https://doi.org/10.7249/RR2409

C. MIB briefing [MIB129] National Institute for Health and Care Excellence, 2017. Health app: Sleepio for adults with poor sleep. https://www.nice.org.uk/advice/mib129

D. 'Enabling better health and self-care at scale with digital sleep medicine' project overview on UKRI website: https://gtr.ukri.org/projects?ref=104187#/tabOverview

E. Report from Oxford AHSN and Big Health on outcomes from Innovate UK project, August 2020: https://www.oxfordhealth.nhs.uk/wp-content/uploads/sites/17/2020/08/Sleepio-in-the-Thames-Valley_Big-Health-and-Oxford-AHSN-case-study_2020.pdf

F. Announcement of free access to Sleepio and Daylight for NHS and support staff during COVID-19 pandemic: https://www.nhsemployers.org/news/2020/03/free-access-to-wellbeing-apps-for-all-nhs-staff

G. Letter from NHS England corroborating importance of University of Oxford studies in choosing Sleepio and Daylight as products to support the mental health of NHS staff

H. (i) Letter from CEO, Big Health, November 2020 and (ii) use of Sleepio and Daylight by NHS staff can be confirmed by Corroborator 1: Implementation Manager, Big Health.

I. Letter from Scottish Government confirming pilot projects to disseminate Sleepio and Daylight in Scotland from December 2020

J. Big Health blog June 2019. 'Announcing our partnership with CVS Health: a giant leap for digital therapeutics'. https://blog.bighealth.com/big-health-cvs-partnership

K. Use of Sleepio and Daylight by CVS Health members can be confirmed by Corroborator 2: UK Director, Big Health.

L. Letter from CVS Health corroborating contribution of University of Oxford studies to impact of Sleepio and Daylight in the US

M. Red Whale CPD website update for GPs (2019). A new screening tool for insomnia. https://www.gp-update.co.uk/_enewsletter/2019/July/WLOGPs%20A%20new%20screening%20tool%20for%20insomnia