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A pilot evaluation of the Sleep Ninja – a smartphone-application for adolescent insomnia symptoms

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Abstract

Objectives: The aim of this study was to test the feasibility, acceptability and preliminary effects of a recently developed smartphone application, Sleep Ninja, for adolescent sleep difficulties.

Setting: The study was conducted online with Australian individuals recruited through the community.

Participants: Participants were 50 young people aged 12-16 years with at least mild symptoms of insomnia.

Design: A single-arm pre-post design was used to evaluate feasibility, acceptability and sleep and mental health variables at baseline and post-intervention.

Intervention: Cognitive Behaviour Therapy for Insomnia (CBT-I) informed the development of the Sleep Ninja. The core strategies covered by the app are psychoeducation, stimulus-control, sleep hygiene, cognitive therapy and relaxation techniques. It includes six training sessions (lessons), a sleep tracking function, recommended bedtimes based on sleep guidelines, reminders to start a wind-down routine each night, a series of sleep tips, and general information about sleep. Users progress through each training session and conclude the six-week program with a black belt in sleep.

Outcome measures: Feasibility was evaluated based on consent rates, adherence and attrition, acceptability was assessed using questionnaires and a post-study interview, and sleep, depression and anxiety variables were assessed at baseline and post-intervention.

Results: Data indicated that the Sleep Ninja is a feasible intervention and is acceptable to young people. Findings showed there were significant improvements on sleep variables including insomnia (within-group effect size d=-0.90), sleep quality (d=-0.46), depression (d=-0.36) and anxiety (d=-0.41).

Conclusions: The Sleep Ninja is a promising intervention for the treatment of sleep difficulties among adolescents. A follow-up randomised controlled trial is now warranted.

Trial registration: Australian New Zealand Clinical Trials Registry (#ACTRN12617000141347).

Article Summary

Strengths and limitations of this study

- This is the first study to evaluate app-delivered Cognitive Behavioural Therapy for Insomnia in adolescents with sleep difficulties.
- The intervention being tested, Sleep Ninja, was developed with input from young people, is fully automated and does not require internet coverage to function.
- The evaluation included measures of feasibility and acceptability as well as detailed semi-structured interviews about participants' experience with the app.
- As a preliminary study, this study did not include a control group.

Clinical insomnia is a sleep disturbance characterised by difficulty falling asleep, staying asleep or waking up too early, with associated daytime impairment (American Psychiatric Association, 2013). It effects approximately 4% of adolescents (Ohayon, Roberts, Zulley, Smirne, & Priest, 2000), however sub-threshold symptoms are very common, with approximately 25% of young people reporting some degree of sleep disturbance (Carskadon, 1990; Ohayon et al., 2000).

Depression and insomnia are closely linked, with comorbidity levels as high as 73% in young people (Liu et al., 2007). Insomnia is not only a symptom of depression, but is a common precursor, with high quality longitudinal data having established insomnia is an independent risk factor for depression onset (Baglioni et al., 2011; Franzen & Buysse, 2008; Riemann & Voderholzer, 2003). For example, a recent meta-analysis found that insomnia was associated with a greater than two-fold increase in depression risk (Baglioni et al., 2011). Depression is now the leading cause of disability in young people worldwide (Gore et al., 2011), and approximately 1 in 5 young people will experience an episode of depression by the time they are 18 years old. The demand for mental health services dramatically outweighs the availability of these services, and current treatments alleviate only 13% of the disease burden (Andrews, Issakidis, Sanderson, Corry, & Lapsley, 2004). Innovative and effective ways to address the depression crisis in young people are needed, and one way to do this may be by targeting sleep disturbance.

In line with this suggestion, there is an emerging literature showing that targeting insomnia in individuals with concurrent insomnia and depression improves both sleep and depression outcomes (Ashworth et al., 2015; Manber et al., 2008; Wagley, Rybarczyk, Nay, Danish, & Lund, 2013). This suggests there may be value in targeting sleep to improve insomnia symptoms, with potential downstream effects on depression. To our knowledge, there have been only two studies, one in adults and one in adolescents, testing the hypothesis

that treating insomnia can prevent depressive symptoms. In the adult study, insomnia treatment led to a significant reduction in depression following the intervention and at 6-month and 18-month follow-up, relative to an active control group (Batterham et al., 2017; Christensen et al., 2016). In the youth study, a face-to-face insomnia intervention was delivered to secondary school students who had insomnia and anxiety. Results showed improvements on sleep and anxiety outcomes, but not symptoms of depression (Blake et al., 2016). Data from the two year follow-up from this study has not yet been published (Waloszek et al., 2015).

The gold standard treatment for insomnia is cognitive behaviour therapy for insomnia (CBT-I), recommended by major medical authorities (Australasian Sleep Association, American College of Physicians), and typically involves a combination of strategies that include psychoeducation, stimulus control, sleep restriction, cognitive therapy, and sleep hygiene. The effectiveness of CBT-I is established among adolescents and adults, and there is evidence from the adult literature to support the use of digitally delivered CBT-I to treat insomnia symptoms (Okajima, Komada, & Inoue, 2011; Zachariae, Lyby, Ritterband, & O'Toole, 2016). Although in its infancy, there are now two studies (one pilot and one randomised controlled trial [RCT]) that have examined the use of internet-delivered CBT-I for adolescents with subthreshold insomnia symptoms and insomnia, respectively, both with positive results (de Bruin, Bogels, Oort, & Meijer, 2015; de Bruin, Oort, Bogels, & Meijer, 2014). However, there are no digitally delivered CBT-I programs that are commercially available for youth at present (Werner-Seidler, Johnston, & Christensen, 2018).

Delivering sleep interventions via digital formats may be particularly well-suited to young people. Today's adolescents have grown up in the digital age and are more comfortable with technology than any previous generation. The move from face-to-face therapies to web-based platforms has been positive — young people overwhelmingly (97%)

show a preference for digital delivery when given the choice between face-to-face and digital CBT-I (de Bruin et al., 2014). This preference may in part be explained by the fact that young people are notoriously reluctant to seek help for psychological issues, for reasons that include stigma and a preference to manage the problem themselves (Gulliver, Griffiths, & Christensen, 2010). Given that fewer than 40% of youth with a mental health problem access professional help (Rickwood, Deane, & Wilson, 2007), focusing on factors such as sleep disturbance as a risk factor for other more stigmatised disorders like depression, offers a potentially more acceptable approach specifically for adolescents.

To meet the need for a widely available adolescent CBT-I program, we used a participatory design process to develop an automated smartphone application (app; Sleep Ninja) to target symptoms of adolescent sleep problems (Werner-Seidler et al., 2017). Using smartphones to deliver CBT-I offers unprecedented convenience, removing barriers such as cost and accessibility. Smartphone ownership levels are now at an all-time high (estimated to be >80%), with approximately 95% of teenagers in English-speaking, developed countries (Australia, Britain, US) having access to a smartphone (Ofcom, 2017; Pew Research Center, 2018; Triton Digital, 2017).

The goal of this pilot study was to examine the acceptability, feasibility and preliminary effects of this intervention delivered to adolescents. In line with the guidelines on the development of behavioural interventions (Craig et al., 2008; Gitlin, 2013), the primary purpose of this study was to investigate recruitment rates, uptake, intervention completion, reasons for non-adherence, and participant retention. The secondary aim was to use both quantitative and qualitative methods to determine the acceptability of the app among young people with sleep problems and allow for the refinement of the intervention prior to a formal randomised evaluation. A final aim was to examine the impact of the Sleep Ninja app on sleep outcomes and mental health symptoms. We used a single-arm, pre-post design to

address these objectives. It was hypothesised that the app would be a feasible modality in which to deliver the automated sleep intervention, as measured by uptake, completion and retention rates, that the app would be acceptable to young people, and that its use would be associated with improvement in sleep and mental health symptoms.

Method

This trial was prospectively registered on the Australian New Zealand Clinical Trials Registry (#ACTRN12617000141347).

Participants

Fifty participants were recruited via media and social media channels, including the Black Dog Institute's website and paid Facebook advertisements that targeted potential participants and their parents. Inclusion criteria were: aged 12-16 years, presence of at least mild insomnia, operationalised by endorsement of at least one of the following symptoms over the preceding two-week period: difficulty falling asleep, difficulty staying asleep or problems waking up too early. These items are the first three questions on the Insomnia Severity Index (Bastien, Vallieres, & Morin, 2001), and were chosen to include a participant group with at least mild levels of insomnia. For study inclusion, participants also needed to own a smartphone running iOS or Android, have a valid email address, access to the internet, and be able to provide personal and parental consent.

Measures

Insomnia Severity Index (ISI). The ISI is a psychometrically sound, seven-item self-report measure of insomnia symptoms over the previous two weeks (Bastien et al., 2001; Chung, Kan, & Yeung, 2011). Responses are reported on a Likert scale from 0 to 4, producing total scores of 0 to 28 (Bastien et al., 2001; Chung et al., 2011). Cut-off scores are as follows: 0-7 reflects no clinically significant insomnia, 8-14 indicates subthreshold

insomnia, 15-21 suggests moderate severity insomnia, and 22-28 indicates severe insomnia (Chahoud, Chahine, Salameh, & Sauleau, 2017).

Pittsburgh Sleep Quality Index (PSQI). The PSQI is a widely used self-report 19-item scale that assesses usual sleep habits and experiences over the preceding month and has been validated in adolescent samples (de la Vega et al., 2015). There are seven sub-scales which are sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medications, daytime dysfunction (Cole et al., 2006). Each component is scored from 0 (no difficulty) to 3 (severe difficulty), which are summed to obtain a Global PSQI score ranging from 0 to 21 (Guo, Sun, Liu, & Wu, 2016).

Patient Health Questionnaire (PHQ-8). The PHQ-8 assesses depressive symptoms in the preceding two weeks (Kroenke et al., 2009). The questions are identical to those asked in the PHQ-9 with the exclusion of the last item which asks about suicide. The PHQ-8 is comparable to the PHQ-9 in terms of diagnosing depressive disorders (Kroenke, Spitzer, & Williams, 2001). Each item is scored on a 4-point scale and summed together to form a total depression score ranging from 0 to 24. Scores correspond to the following cut-offs: 0-9 indicates minimal symptoms, 10-14 indicates mild symptoms, 15-19 reflects moderate symptoms, and 20-24 is indicative of severe depression. The PHQ-8 has demonstrated good sensitivity (70%) and high specificity (98%) for major depression for scores ≥10 (Kroenke et al., 2009).

Generalised Anxiety Disorder 7-item (GAD-7). The GAD-7 evaluates symptoms of generalised anxiety disorder (Spitzer, Kroenke, Williams, & Lowe, 2006). All items are scored on a scale from 0 (not at all) to 3 (nearly every day). The scores on each item are summed together to derive a total score, ranging from 0 to 21 of which 0-4 indicates minimal anxiety, 5-9 mild anxiety, 10-14 moderate anxiety, and 15-21 severe anxiety.

Expectations of Success. A four-item scale was developed for this study to assess participants' motivation and expectations for improving their sleep with an app (e.g., *I am confident that people could learn skills for improving sleep from an app*). The Expectation of Success measure was scored on a five-point scale and total scores were computed by summing each item, ranging from 0 to 16. Higher scores on this scale indicate greater confidence and readiness to target sleep using a smartphone app.

Acceptability of the Intervention. The Acceptability of the Intervention scale is a seven-item measure that was developed by the research team to assess participants' attitudes and behaviours associated with using the app (e.g., *How much did you learn from the app* and *Would you recommend this program to others?)*. This measure was informed by similar acceptability measures commonly used in the field (Thorndike et al., 2008). Each item was designed to assess a different domain (such as app usefulness, ease of use, comprehension), and therefore item scores were considered separately.

Reasons for Non-Adherence. The Reasons for Non-Adherence measure is a 23-item scale that was developed by the researchers to assess the degree to which different reasons impacted on participants' use of the app. Examples of domains assessed included technical problems with the app and difficulty with the material. The scores on each item were considered separately.

Sleep Diary. The ten-item Sleep Diary was developed by the research team incorporating the questions from the Consensus Sleep Diary (Carney et al., 2012), with the addition of two questions regarding daytime naps and use of sleep medication. Participants answered 10 questions which included bedtime, time taken to fall asleep (sleep onset latency; SOL), number and duration of night-time awakenings (number of awakenings; NWAK, duration of wakefulness after sleep onset; WASO), time of final awakening, time participants got out of bed for the day, subjective sleep quality, how refreshed participants felt upon

awakening, duration of any daytime naps and use of sleep medication. From the sleep diary we calculated time in bed (TIB), total sleep time (TST; calculated by subtracting SOL, WASO and time between waking and getting up in the morning, from TIB) and sleep efficiency (SE; calculated by taking the percentage of TST/TIB).

Post-Study Interview. After study completion, participants were invited to attend a face-to-face or telephone interview to provide feedback on their experience. Interviews were semi-structured and explored participants' opinions about the study in general, and specifically in relation to the intervention. Questions were open-ended, and flexible enough to explore ideas that were raised during each interview. Interviews were audio recorded and then transcribed verbatim by the interviewer. The interview content was pragmatically coded into relevant themes by the same researcher, with oversight and guidance provided by the research team.

Intervention – 'Sleep Ninja'

The Sleep Ninja app was derived from CBT-I and developed by our team, as a fully-automated smartphone app. Young people contributed to the content, functionality and accessibility/user experience of the app through a series of focus groups (Werner-Seidler et al., 2017). The core strategies included in the app were: psychoeducation, stimulus-control, sleep hygiene, cognitive therapy and relaxation techniques. Sleep restriction was deliberately omitted because some support (parental and/or professional) is likely to be required to successfully implement sleep restriction (particularly in young people).

The structure of the Sleep Ninja app includes six training sessions (lessons), a sleep tracking function, recommended bedtimes based on sleep guidelines, reminders to start a wind-down routine each night, a series of sleep tips, and general information about sleep. The home screen has 3 options: Train, Track, and More (see Figure 1). Users complete training sessions which are delivered through a chat-bot format where the sleep ninja essentially acts

as a sleep coach. Training sessions take approximately 5-10 minutes to complete, and cover: psychoeducation (training 1), stimulus control (training 2), sleep hygiene (training 3), identifying and planning for high-risk situations (training 4), cognitive therapy (training 5), and a final review session (training 6). The user interacts with the app through a forced choice chat-bot format which is responsive to the input of the user, meaning it personalises information and recommendations based on the selections and sleep profile recorded by the participant. Users level up and reach their next "belt" by completing one training session and tracking their sleep for 3 nights (out of a 7-night period). As there were six training sessions to complete, the app was made available for six weeks (42 days) before it locked. Users finish the program with a black belt in sleep.

Procedure

All procedures were approved by the University of New South Wales Human Research Ethics Committee (HC#16702). Participants were encouraged to download consent forms if they met the eligibility criteria listed on the study website and submit this directly to the research team, once completed. Those who provided written informed consent and that of a parent or guardian were then enrolled in the trial and invited to complete the screening questions to verify study eligibility, before completing baseline questionnaires which included: demographics, ISI, PSQI, PHQ-8, GAD-7 and Expectation of Success. Participants could then access the first day of the online seven-day sleep diary. Another diary entry became available each day for the following six days and participants were reminded to complete entries via text-message. At the completion of seven entries in the diary, participants were given access to the Sleep Ninja app on their personal smartphone devices. Participants could use the app for six weeks before the post study questionnaire was made available, which included the same battery as baseline with the omission of the Expectations of Success questionnaire and with the addition of the Acceptability and Reasons for Non-

Adherence questionnaires. Participants then completed another seven-day sleep diary, which was delivered in the same format and schedule as baseline. After the study had finished, participants were invited to participate in a face-to-face or telephone interview to provide feedback on their experience of participating in the study. Participants were reimbursed for their time with giftcards to the value of $10 each for completing baseline and post-study assessment schedules; $20 for a telephone interview and $30 for a face-to-face interview.

Patient and Public Involvement

Prior to this study, a separate group of young people were consulted in a series of focus groups to inform the design, features and structure of the app (for more information please see Werner-Seidler et al., 2017). As a feasibility and acceptability study, participants were asked to report on their experiences with respect to both the app and the study procedures, via questionnaires and an in-depth semi-structured interview. Given that a key objective of this study was to assess the acceptability of the Sleep Ninja app, participants' perspectives were of critical importance. A one-page lay summary of the study results has been sent to all participants.

Statistical Analyses

Statistical significance was set at α=.05. Sleep diary variables were averaged across each time point (baseline, post-study) to create summary scores. All questionnaire and sleep diary variables were initially screened for excessive skew (>3) or kurtosis (>8; Kline, 2011). Four sleep diary entries did not pass screening and were further scrutinised (baseline: WASO entry; post-study: SOL, TST, SE entries). Examination of these four entries revealed each had an extreme value (*z*-scores ranged from |4.11| to |6.05|) and a decision was made to remove these four values. Subsequently all variables had satisfactory skew and kurtosis.

Questionnaire and sleep diary variables were examined using multilevel modelling. This modelling approach handles missing data by incorporating all available data from each

subject into the analysis. Given the aims of our study, our interest centred on the main effect of time (i.e., change from baseline- to post). Random effects were modelled for intercept and time. Models were respecified with a random effect for intercept only in cases where there was no variation in individual baseline- to post-study changes. Within-group effect sizes were computed as the modelled mean difference between baseline and post-study divided by the sample standard deviation at baseline.

Results

Baseline Characteristics

See Table 1 for characteristics of the study sample. Participants had a mean age of 13.71 (*SD*=1.35), were spread across school grade, and nearly all were born in Australia and living in the city. Most participants reported difficulty falling asleep, with about half also reporting problems staying asleep or waking up too early, and about a quarter of the sample were receiving treatment for sleep or a mental health problem.

Table 1. Demographic Variables

Characteristics	Sample ($N = 50$)
Age in years, mean (*SD*, range)	13.71 (1.35, 12-16)
Age in years, n (%)	
12	10 (20.4%)
13	15 (30.6%)
14	7 (14.3%)
15	12 (24.5%)
16	5 (10.2%)
Female, *n* (%)	33 (66%)
Born in Australia, *n* (%)	47 (94%)
Live in the city, *n* (%)	44 (88%)
Sleep problems, *n* (%)	
Difficulty falling asleep	47 (94%)
Difficulty staying asleep	28 (56%)
Problems waking up too early	28 (56%)
Receiving treatment for sleep or mental health problem, *n* (%)	13 (26%)

Note. One participant did not indicate their age, so $n = 49$ for age.

Recruitment Rate

There were more than 300 enquires made to the research team about participation in this trial. Of these, 60 individuals indicated eligibility and returned consent forms. Ten of these participants were not enrolled in the trial; four did not meet inclusion criteria and six withdrew prior to the trial. Reasons for withdrawing were: a change of mind (n=1), a lack of time (n=2), considering participation a chore (n=1), confidentiality concerns (n=1). One participant did not provide a reason. Therefore, 89% (n=50) of the 56 young people who provided consent and met screening criteria continued to trial. See Figure 2 CONSORT diagram for details.

Expectation of Success

Overall, participants were optimistic about using the app, with a mean score of 12.90 (*SD*=2.09) out of a possible 16 points. Every single participant agreed that in principle, people could learn skills for improving sleep from an app, and indicated that they felt that study participation was important. All participants reported that improving their sleep habits were important, with 49% indicating it was 'very important'. Finally, the sample demonstrated their readiness for change by indicating that they were at least moderately ready to improve their sleep patterns using an app.

Retention

Of the 50 participants in the study sample, 47 (94%) completed the baseline questionnaire and sleep diaries and were invited to download the Sleep Ninja. At post-study, 34 participants completed the post-study battery (72% retention). Participants who had available data at both time-points did not differ significantly from those who only had baseline data on any of the questionnaires or sleep diary measures (all Fs < 2.58, p > .115).

Uptake and Adherence

Forty-five participants (96%) who completed the baseline assessment downloaded the Sleep Ninja. Program usage data indicated that of these, 82% completed the first lesson, 51% completed four of the six lessons, and 33% completed all six. Participants were accurate in their reporting of app use, with approximately 80% of participants indicating that they completed 'most' or 'almost all' of the app.

Acceptability

Survey responses on the Acceptability of the Intervention questionnaire indicated that young people overwhelmingly reported that the app was 'easy' or 'very easy' to use (97%). The majority of participants (59%) indicated that they learnt 'a fair bit' from the app, and 28% reported that they learnt 'a great deal', while 12% did not learn very much or almost nothing. Participants found the app to be either 'useful' or 'very useful' (78%), while the remainder (22%) did not find it useful. Most respondents (72%) reported changing their behaviour after using the app, and examples of behaviour change included changes to their pre-bedtime routine (22%), keeping more consistent sleep-wake cycles (65%), getting up earlier in the morning (22%), and restricting the use of their bed for sleep (30%). More than half of the participants reported that they would use this kind of app in the future (56%), and encouragingly, 91% would recommend the Sleep Ninja app to a friend.

The interview mirrored the findings of the questionnaire in terms of acceptability and usefulness. However, there were some aspects of the app that users felt could be improved. Specifically, interviewees expressed a desire for improved explanation of the different app sections and what they needed to do each time they opened the app. Participants commonly reported wanting to be able to personalise their user experience more, including skipping information they knew, seeking more information around difficult or unfamiliar topics, accessing information in different formats (e.g. video/audio), being able to speed up or slow

down the Sleep Ninja's speech, and being able to update their wind-down activity choices and the time the reminder appeared.

Reasons for Non-Adherence

Results from this questionnaire indicated that young people were overwhelmingly happy to use an app to receive help for their sleep issues (84%), did not have technical issues with its use (75%), and felt they had the technical skills to use the app (90%). Participants all reported that the material was relevant and conceptually easy to understand. The main reasons participants reported not using the app was that they felt it took too long to work through (53%), there was too much text to read (47%), and that it was too repetitive (59%).

Preliminary Effects

Sleep and Mental Health Questionnaire Outcomes. Table 2 shows the results for the questionnaire measures. As predicted, from baseline- to post-study, there was a significant decrease in insomnia severity measured by the ISI, β=-4.29, p<.001, d=-0.90, and sleep quality on the PSQI, β=-1.88, p<.001; d=-0.46. Similarly, mental health measures showed a decrease in both depression on the PHQ-A, β=-2.60, p<.001, d=-0.36 and anxiety on the GAD-7, β=-2.56, p<.001, d=-0.41.

Table 2. Questionnaire Measures

	Pre-intervention		*Post-intervention*		*Modelled change from pre- to post-intervention*	
Outcome	*n*	*M (SD)*	*n*	*M (SD)*	β [95% CI]	*d*
ISI	50	14.12 (4.75)	34	9.62 (5.23)	-4.29 [-5.63, -2.95]***	-0.90
PSQI	50	10.43 (4.12)	33	8.03 (4.08)	-1.88 [-2.85, -0.90]***	-0.46
PHQ-A	49	13.04 (7.24)	32	9.88 (7.53)	-2.60 [-3.99, -1.22]***	-0.36
GAD-7	49	9.92 (6.19)	32	7.09 (6.13)	-2.56 [-3.59, -1.52]***	-0.41

Note. Raw means (SDs) are presented. Cohen's *d* values are time effects for pre-intervention to post-intervention using the modelled mean difference divided by the sample pre-intervention SD. ISI = Insomnia Severity Index; PSQI = Pittsburgh Sleep Quality Index; PHQ-A = Patient Health Questionnaire modified for Adolescents; GAD-7 = Generalised Anxiety Disorder 7-item.
*** p < .001.

Sleep Diary Outcomes. Results for the sleep diary entries are shown in Table 3. At baseline, participants reported taking an average of one hour and 12 minutes to fall asleep, spent an average of 9 hours and 39 minutes in bed, woke up an average of 1.47 times, and slept for a total of seven hours and 40 minutes. Overall sleep efficiency was just above 80%. Results from the analysis indicated that as predicted, there was a significant decrease of 21 minutes in how long participants took to fall asleep (SOL; β=-0.37, p=.032) and how frequently they woke during the night reducing to an average of 0.87 times (NWAK; β=-0.46, p=.011). There were also improvements in total sleep time of 33 minutes (TST; β=0.53, p=.005), SE (β=5.25, p=.016), how refreshing sleep was (β=0.43, p=.001) and sleep quality (β=0.31, p=.018). There were no significant differences in TIB, WASO or medication use (all ps>.05). Within-group Cohen's d effect sizes ranged from small to medium (0.31-0.68).

Table 3. Sleep Diary Measures

	Pre-intervention		*Post-intervention*		*Modelled change from pre- to post-intervention*	
Outcome	*n*	*M (SD)*	*n*	*M (SD)*	*β* [95% CI]	*d*
Sleep Diary						
TIB (h:min)	48	9:39 (1:11)	29	9:38 (0:55)	-0.01 [-0.42, 0.41]	-0.01
SOL (h:min)	48	1:12 (1:01)	28	0:51 (0:47)	-0.37 [-0.70, -0.03]*	**-0.36**
WASO (h:min)	47	0:14 (0:14)	29	0:12 (0:14)	-0.04 [-0.12, 0.05]	-0.17
TST (h:min)	48	7:40 (1:09)	28	8:13 (1:06)	0.53 [0.17, 0.90]**	**0.46**
NWAK	48	1.47 (1.50)	29	0.87 (1.35)	-0.46 [-0.81, -0.11]*	**-0.31**
SE (%)	48	80.12 (12.01)	28	85.64 (11.30)	5.25 [1.03, 9.47]*	**0.44**
Sleep refreshingness	48	2.37 (0.63)	29	2.78 (0.78)	0.43 [0.19, 0.68]***	**0.68**
Sleep quality	48	2.84 (0.74)	29	3.10 (0.82)	0.31 [0.06, 0.56]*	**0.42**
Use of medication	48	0.12 (0.30)	29	0.11 (0.30)	-0.01 [-0.02, 0.01]	-0.03

Note. Raw means (SDs) are presented. Cohen's *d* values are time effects for pre-intervention to post-intervention using the modelled mean difference divided by the sample pre-intervention SD. Time variables (TIB, SOL, WASO, TST) are expressed in hours:minutes. SE is expressed as a percentage. Refreshingness of sleep is rated on a Likert scale from 1 = *Exhausted* to 5 = *Very refreshed.* Quality of sleep is rated on a Likert scale from 1 = *Very Poor* to 5 = *Very Good*. Use of medication is expressed as a proportion of days medication was used to help with sleep. TIB = Time in bed; SOL = Sleep onset latency; NWAK = Number of awakenings; WASO = Wake after sleep onset; TST = Total sleep time; SE = Sleep efficiency.

* $p < .05$, ** $p < .01$, *** $p < .001$.

Discussion

The purpose of this pilot study was to evaluate the feasibility, acceptability and preliminary effects of the Sleep Ninja app on sleep and mental health symptoms, for use among adolescents with insomnia symptoms. A secondary objective of the study was to gather information in order to refine aspects of the app before evaluating it in a larger trial. Our findings confirmed that young people with sleep disturbance were optimistic about using the app and could complete baseline questionnaires and sleep diaries using an automated digital format without assistance. Feasibility was confirmed based on uptake, completion and retention rates with young people volunteering for the study, downloading the app and completing most of the lessons. This provides evidence that the Sleep Ninja app is a feasible intervention to deliver to young people experiencing sleep difficulties.

Our results also indicate that the app was acceptable and engaging as demonstrated through the acceptability questionnaire and post-study interviews. Overall, adolescents reported that the app was easy to use and contained material relevant to their sleep issues, which resulted in sleep-related behaviour change by the conclusion of the study. Findings identified several areas for improvement and refinement of the app. Specifically, the main reason participants stopped using the app was due to the amount of text presented in the app and the repetitive nature of the material. Participants also requested an improved onboarding process to explain the app components, as well as a more tailored experience. Therefore, refining the app taking these points into account is likely to increase adherence and engagement with the content.

Efficacy outcomes showed that insomnia symptoms improved significantly from baseline to post-study, effectively moving participants from the lower cut off for clinical insomnia, firmly into the sub-threshold symptom level. There was an improvement in self-reported sleep quality, with a medium effect size (d=-0.46) suggesting app use improves

quality of sleep. This suggests that the program has benefits beyond just insomnia, which is consistent with research indicating that insomnia and other sleep disturbances (e.g. delayed sleep phase disorder, irregular sleep wake presentations) share common processes and symptoms (Harvey, 2009). The improvements detected on the two sleep questionnaire measures (ISI, PQSI) were corroborated by those found in the sleep diaries, with participants falling asleep more quickly at night, waking less frequency, sleeping for longer and reporting improved sleep efficiency and quality. Findings on these sleep outcomes are consistent with the two studies which have evaluated web-delivered CBT-I for adolescents with insomnia (de Bruin et al., 2015; de Bruin et al., 2014), and show for the first time that CBT-I, when delivered to adolescents by smartphone-app, confer benefits for sleep disturbance. It is encouraging that the within-group effect size obtained in the current study for insomnia (d=-0.90) is comparable to within-group effect size found for digitally-delivered CBT-I in a randomised trial (d=-0.92) (de Bruin et al., 2015). In this randomised study, the intervention group was found to be superior to the waitlist control, suggesting that a within-group effect size of this magnitude is likely to reflect improvement over and above what would be expected based on a standard placebo effect (de Bruin et al., 2015). Beyond the sleep outcomes, we also found that there were decreases in depression and anxiety symptoms following the completion of the intervention suggesting that there may be value in using this app to address mental illness. The magnitude of the decrease in depression scores is notable, with individuals moving from the moderate range into the mild range, and a within-group effect size that is comparable to other adolescent depression prevention trials (Horowitz, Garber, Ciesla, Young, & Mufson, 2007). These findings provide proof-of-principle evidence that the Sleep Ninja app may be useful in addressing depression. As a pilot study, we did not test the specific hypothesis that targeting insomnia will decrease depression risk, but given our encouraging findings, a follow-up randomised controlled trial which follows participants

over time and assesses depression risk is now warranted. This study makes a unique contribution to the literature by showing that smartphone delivery of CBT-I is a promising format in which to deliver this gold-standard intervention. This is the first study that we are aware of that has evaluated app-delivered CBT-I in young people (Werner-Seidler et al., 2018), and only the second study that has tested mobile phone delivery of CBT-I, the first study being conducted in adults, with positive effects on sleep outcomes (Horsch et al., 2017). Using smartphones to deliver interventions such as this offer a myriad of advantages, including immediate connectivity to automated interactive applications that can be accessed anytime, anywhere. Sleep Ninja has been developed so that it does not rely on internet access for use, which is likely to be important to young people who may have limited data plans, and individuals who do not have optimal internet coverage. Not requiring internet coverage to access digital programs represents a new wave of flexibility in the delivery of health interventions and the automated nature of the intervention means it can be delivered without professional support. It is notable that we had a 72% retention rate, which is at the upper level of that detected for digital interventions which has been shown in a meta-analysis to range between 43-99% (Helen Christensen, Griffiths, & Farrer, 2009), with retention rates typically lower in non-supported interventions (Andersson & Cuijpers, 2009).

There are several study limitations that need to be considered. First, participants in this trial were required to have relatively minor levels of insomnia symptoms for study entry. This decision was made by balancing inclusiveness against the requirement of sleep disturbance to ensure participants were motivated to use the app. Moreover, given the study focus was on feasibility and acceptability, we felt it would be prudent to establish these factors before targeting a more severe participant group. That said, while we set the threshold for entry relatively low, both the mean and the median converged on an ISI score of just above 14, indicating that participants were at the junction between having subthreshold and

clinical levels of insomnia symptoms (cut-off score is 15). Therefore, it is relatively unlikely that there would have been a floor effect as the data showed there was sufficient room to detect symptom-improvement. The high mean symptom level also suggests that the results may generalise to a group with clinical levels of insomnia. Second, we did not include a control group. Again, as the study goal was to establish feasibility and acceptability, it was not necessary to include a control group for this purpose. However, this design is not able to attribute causality to the intervention and a controlled study is now needed. Finally, this study relied exclusively on subjectively reported sleep outcomes. Although objective measures such as polysomnography provide the most accurate way to assess sleep, there is evidence that subjectively measured sleep variables could be more closely associated with functional outcomes (Wilson, Fung, Walker, & Barnes, 2013). Moreover, subjectively experienced sleep quality and parameters have consistently shown to be strongly associated with psychological wellbeing (Fuligni & Hardway, 2006; Lund, Reider, Whiting, & Prichard, 2010), suggesting that perception of sleep is as important, if not more so, than objective measures. We are currently investigating how inbuilt smartphone sensors such as the accelerometer might be used to provide a more objective estimate of sleep.

This study provides preliminary evidence supporting the feasibility, acceptability and effects of a fully-automated app that targets adolescent sleep disturbance. The Sleep Ninja intervention shows promise both as a sleep-focused intervention, but also potentially to reduce risk for depression onset.

Figure Legends

Figure 1. Example screens from the Sleep Ninja app. From left: Homescreen, Training Session Access and Progress Record, Tracking and Bedtime Setting, More Information

Figure 2. Participant Flow

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Author Statement

AW-S, BO, MT and HC conceived of the study and the trial design. AW-S designed the study with input from all authors, and oversaw the management of the trial. LJ led trial recruitment, managed the day-to-day running of the trial and conducted the participant interviews. QW conducted the analyses with assistance from AW-S and LJ. All authors contributed to the preparation of the manuscript.

Competing Interests Statement

No competing interests to declare.

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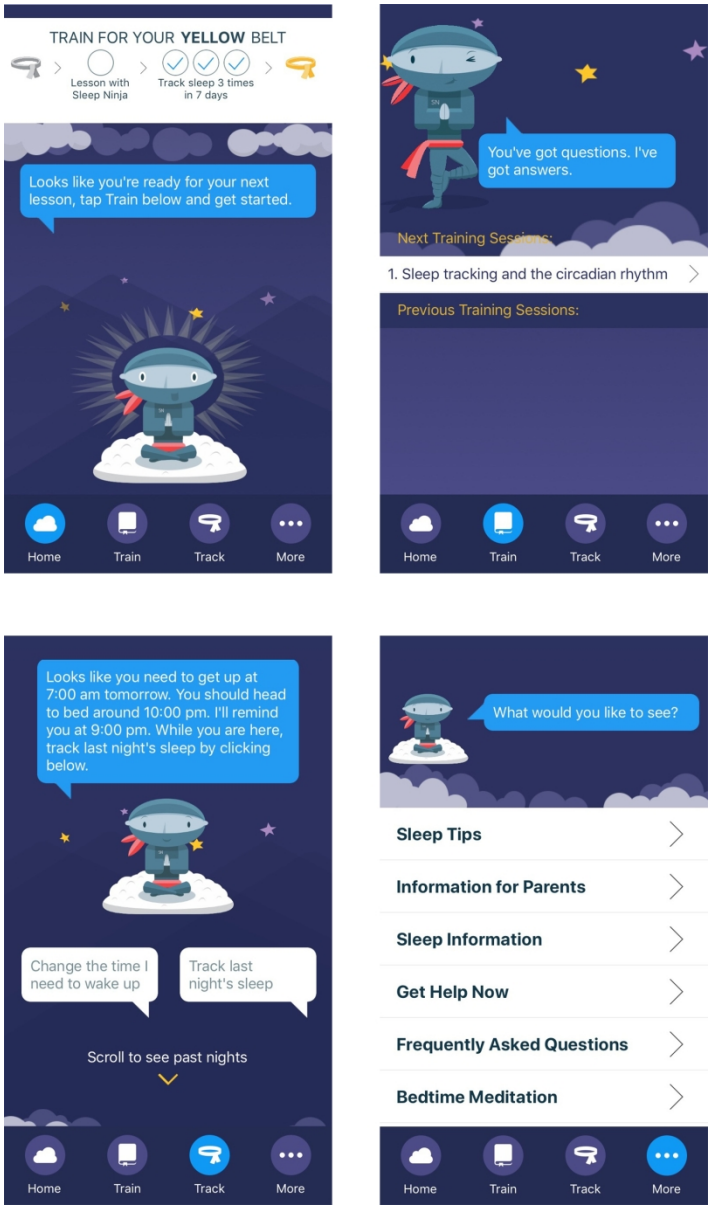

Figure 1. Example screens from the Sleep Ninja app. From left: Homescreen, Training Session Access and Progress Record, Tracking and Bedtime Setting, More Information

139x238mm (300 x 300 DPI)

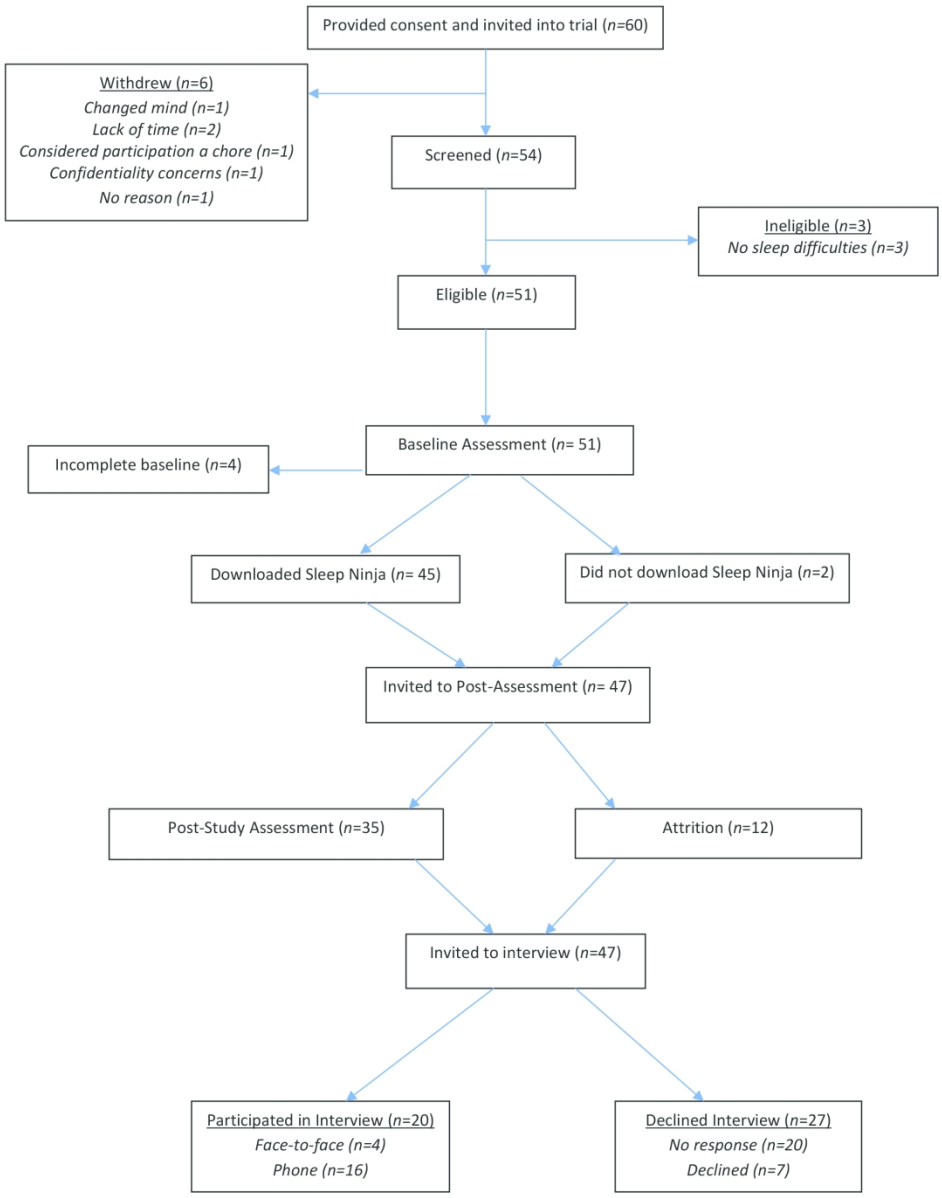

Figure 2. Participant Flow

187x238mm (300 x 300 DPI)

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A pilot evaluation of the Sleep Ninja – a smartphone-application for adolescent insomnia symptoms

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A pilot evaluation of the Sleep Ninja – a smartphone-application for adolescent insomnia symptoms

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Abstract

Objectives: The aim of this study was to test the feasibility, acceptability and preliminary effects of a recently developed smartphone application, Sleep Ninja, for adolescent sleep difficulties.

Setting: The study was conducted online with Australian individuals recruited through the community.

Participants: Participants were 50 young people aged 12-16 years with sleep difficulties.

Design: A single-arm pre-post design was used to evaluate feasibility, acceptability and sleep and mental health variables at baseline and post-intervention.

Intervention: Cognitive Behaviour Therapy for Insomnia (CBT-I) informed the development of the Sleep Ninja. The core strategies covered by the app are psychoeducation, stimulus-control, sleep hygiene, and sleep-related cognitive therapy. It includes six training sessions (lessons), a sleep tracking function, recommended bedtimes based on sleep guidelines, reminders to start a wind-down routine each night, a series of sleep tips, and general information about sleep. Users progress through each training session and conclude the six-week program with a black belt in sleep.

Outcome measures: Feasibility was evaluated based on consent rates, adherence and attrition, acceptability was assessed using questionnaires and a post-study interview, and sleep, depression and anxiety variables were assessed at baseline and post-intervention.

Results: Data indicated that the Sleep Ninja is a feasible intervention and is acceptable to young people. Findings showed there were significant improvements on sleep variables including insomnia (within-group effect size d=-0.90), sleep quality (d=-0.46), depression (d=-0.36) and anxiety (d=-0.41).

Conclusions: The Sleep Ninja is a promising intervention that could assist adolescents who experience sleep difficulties. A follow-up randomised controlled trial is now warranted.

Trial registration: Australian New Zealand Clinical Trials Registry (#ACTRN12617000141347).

Article Summary

Strengths and limitations of this study

- This is the first study to evaluate app-delivered Cognitive Behavioural Therapy for Insomnia in adolescents with sleep difficulties.
- The intervention being tested, Sleep Ninja, was developed with input from young people, is fully automated and does not require internet coverage to function.
- The evaluation included measures of feasibility and acceptability as well as detailed semi-structured interviews about participants' experience with the app.
- As a preliminary study, this study did not include a control group.

Clinical insomnia is a sleep disturbance characterised by difficulty falling asleep, staying asleep or waking up too early, with associated daytime impairment [1]. It effects approximately 4% of adolescents [2], however sub-threshold symptoms are common, with approximately 25% of young people reporting some degree of sleep disturbance [2, 3].

Depression and insomnia are closely linked, with comorbidity levels as high as 73% in young people [4]. Insomnia is not only a symptom of depression, but is a common precursor, with high quality longitudinal data having established insomnia as an independent risk factor for depression onset [5, 6, 7]. For example, a recent meta-analysis found that insomnia was associated with a greater than two-fold increase in depression risk [5]. Although depression has multiple causes and maintaining factors that go beyond the presence of sleep problems, the literature suggests that sleep plays an important role, and targeting sleep in the context of depression may have wide-reaching benefits.

There is emerging evidence that addressing insomnia in individuals with concurrent insomnia and depression improves both sleep and depression outcomes [8, 9, 10]. This suggests there may be value in targeting sleep to improve insomnia symptoms, with potential downstream effects on depression. To our knowledge, there have been three studies testing the hypothesis that targeting insomnia can prevent depressive symptoms. In an adult study, insomnia treatment led to a reduction in depression following the intervention and at 6 and 18-month follow-up, relative to an active control group [11, 12]. In a youth study, a face-to-face insomnia intervention was delivered to secondary school students and results showed improvements on sleep and anxiety outcomes, but not symptoms of depression [13]. Data from the two-year follow-up from this study has not yet been published [14]. In a second youth study, a sleep intervention delivered either in group format or digitally led to decreased depressive symptoms at both 2 and 12-month follow-up, an effect that was mediated by improvements in insomnia [15].

The gold standard treatment for insomnia is cognitive behaviour therapy for insomnia (CBT-I; Australasian Sleep Association, American College of Physicians), and there is accumulating evidence to support the use of digitally delivered CBT-I in both adults and young people [16, 17, 18, 19]. Delivering sleep interventions via digital formats may be particularly well-suited to young people, with adolescents showing a strong preference (97%) for digital delivery when given the choice between face-to-face and digital CBT-I [17]. This preference may in part be explained by the fact that young people are reluctant to seek help for psychological issues, for reasons that include stigma and a preference to manage the problem themselves [20]. Sleep is typically less stigmatised than disorders like depression, suggesting that it may be more appealing to adolescents. Currently, there are no digital CBT-I programs that are commercially available for youth [21]. To overall objective of this study was to evaluate a newly-developed digital CBT-I program for adolescents with sleep difficulties.

The aim of this pilot study was to examine the acceptability, feasibility and preliminary effects of an intervention (Sleep Ninja) delivered to adolescents via smartphones. In line with the guidelines on the development of behavioural interventions [22, 23], the primary purpose of this study was to investigate recruitment rates, uptake, intervention completion, reasons for non-adherence, and participant retention. The secondary aim was to use both quantitative and qualitative methods to determine the acceptability of the app among young people with sleep difficulties and allow for the refinement of the intervention prior to a formal randomised evaluation. A final aim was to examine the impact of the Sleep Ninja app on sleep outcomes and mental health symptoms. We used a single-arm, pre-post design to address these aims. It was hypothesised that the app would be a feasible modality in which to deliver the automated sleep intervention, as measured by uptake, completion and retention

rates, that the app would be acceptable to young people, and that its use would be associated with improvement in sleep and mental health symptoms.

Method

This trial was prospectively registered on the Australian New Zealand Clinical Trials Registry (#ACTRN12617000141347).

Participants

Fifty participants were recruited via media and social media channels, including the Black Dog Institute's website and paid Facebook advertisements that targeted potential participants and their parents. Inclusion criteria were: aged 12-16 years, presence of at least mild insomnia, operationalised by endorsement of at least one of the following symptoms over the preceding two-week period: difficulty falling asleep, difficulty staying asleep or waking up too early. These items are the first three questions on the Insomnia Severity Index [24], and were chosen to include a participant group with at least mild levels of insomnia. For study inclusion, participants also needed to own a smartphone running iOS or Android, have a valid email address, access to the internet, and be able to provide personal and parental consent.

Measures

Insomnia Severity Index (ISI). The ISI is a psychometrically sound, seven-item self-report measure of insomnia symptoms over the previous two weeks [24, 25]. Responses are reported on a Likert scale from 0 to 4, producing total scores of 0 to 28 [24, 25]. Cut-off scores are as follows: 0-7 reflects no clinically significant insomnia, 8-14 indicates subthreshold insomnia, 15-21 suggests moderate severity insomnia, and 22-28 indicates severe insomnia [24]. The ISI was designed for use in adults but has been widely

administered to, and validated in, adolescent samples [25, 26, 27]. In one adolescent validation study, reliability was strong (Cronbach's α=0.83), and test-retest reliability was acceptable, *r*=.79 [25].

Pittsburgh Sleep Quality Index (PSQI). The PSQI is a widely used self-report 19-item scale that assesses usual sleep habits and experiences over the preceding month and has been validated in adolescent samples, with strong internal consistency (α=.72) and test-retest reliability over a 6-week period (*r*=.81) [28]. There are seven sub-scales which are sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medications, daytime dysfunction [29]. Each component is scored from 0 (no difficulty) to 3 (severe difficulty), which are summed to obtain a Global PSQI score ranging from 0 to 21 [30].

Patient Health Questionnaire – Adolescent Version (PHQ-A). The PHQ-A assesses depressive symptoms in the preceding two weeks in adolescents, and has been adapted from the widely used PHQ-9 designed for adults [31]. This measure has excellent psychometric properties, including α= 0.89, and test-retest reliability of *r*=0.84 [32]. In this study, we used the 8-item version in which the questions are identical to those asked in the PHQ-9 with the exclusion of the last item which asks about suicide and is comparable to the PHQ-9 in terms of diagnosing depressive disorders [32, 33]. Each item is scored on a 4-point scale and summed together to form a total depression score ranging from 0 to 24. Scores correspond to the following cut-offs: 0-9 indicates minimal symptoms, 10-14 indicates mild symptoms, 15-19 reflects moderate symptoms, and 20-24 is indicative of severe depression [31]. The PHQ-A has demonstrated good sensitivity (73%) and high specificity (94%) for major depressive disorder [31].

Generalised Anxiety Disorder 7-item (GAD-7). The GAD-7 evaluates symptoms of generalised anxiety disorder [34]. All items are scored on a scale from 0 (not at all) to 3

(nearly every day). The scores on each item are summed together to derive a total score, ranging from 0 to 21 of which 0-4 indicates minimal anxiety, 5-9 mild anxiety, 10-14 moderate anxiety, and 15-21 severe anxiety [34]. The GAD-7 has good sensitivity (89%) and specificity (82%) for GAD scores >10 [34]. The measure has also been validated in adolescent populations with Cronbach's α=0.90 and high convergent and discriminant validity [35].

Expectations of Success. A four-item scale was developed for this study to assess participants' motivation and expectations for improving their sleep with an app (e.g., *I am confident that people could learn skills for improving sleep from an app*). The four items assessed perceived confidence, importance, usefulness and readiness to change. The Expectation of Success measure was scored on a five-point scale and total scores were computed by summing each item, ranging from 0 to 16. Higher scores on this scale indicate greater confidence and readiness to target sleep using a smartphone app.

Acceptability of the Intervention. The Acceptability of the Intervention scale is a seven-item measure that was developed by the research team to assess participants' attitudes and behaviours associated with using the app (e.g., *How much did you learn from the app* and *Would you recommend this program to others?)*. This measure was informed by similar acceptability measures commonly used in the field [36]. Each item was designed to assess a different domain. The first four domains to be assessed were app completion, ease of use, amount learnt and usefulness, with each being scored on an ordinal scale from 0-3. The final three items assessed behaviour change, whether the participant would use an app like this in the future, and whether they would recommend it to a friend, and were scored dichotomously as either yes or no, with an option for participants to describe the nature of their behaviour change if yes. As each question assessed a different domain, item scores were considered separately.

Reasons for Non-Adherence. The Reasons for Non-Adherence measure is a 23-item scale that was adapted from a previous measure [37] to assess the degree to which different reasons impacted on participants' use of the app. There are four domains assessed: phone/internet/technical issues *(e.g., My phone wasn't working or was having problems);* personal issues *(e.g., I didn't think I deserved help);* intervention-general issues *(e.g., I wasn't convinced the app would be helpful);* and intervention-specific issues *(e.g., There was too much text to read).* Participants responded on an ordinal scale indicating whether each item played no, a little or major part in why they stopped or had difficulty using the app as intended. The scores on each item were considered separately.

Sleep Diary. The ten-item Sleep Diary was developed by the research team incorporating the questions from the Consensus Sleep Diary [38], with the addition of two questions regarding daytime naps and use of sleep medication. Participants answered 10 questions which included bedtime, time taken to fall asleep (sleep onset latency; SOL), number and duration of night-time awakenings (number of awakenings; NWAK, duration of wakefulness after sleep onset; WASO), time of final awakening, time participants got out of bed for the day, subjective sleep quality, how refreshed participants felt upon awakening, duration of any daytime naps and use of sleep medication. Sleep diaries were completed electronically with pre-set categories from which users selected responses from a drop-down menu. A clock scroller was used to enter the time and/or duration of all sleep-related activities and all times were entered in 12-hour format to minimise errors associated with 24-hour time. Restrictions were set to ensure participants could not enter a wake time earlier than bedtime and visa versa. All questions required answers for the sleep diary to be submitted. From the sleep diary we calculated time between waking in the morning and getting out of bed, time in bed (TIB), total sleep time (TST; calculated by subtracting SOL, WASO and

time between waking and getting up in the morning, from TIB) and sleep efficiency (SE; calculated by taking the percentage of TST/TIB).

Post-Study Interview. After study completion, participants were invited to attend a face-to-face or telephone interview to provide feedback on their experience. Interviews were semi-structured and explored participants' opinions about the study in general, and specifically in relation to the intervention. Questions were open-ended, and flexible enough to explore ideas that were raised during each interview. Interviews were audio recorded and then transcribed verbatim by the interviewer. The interview content was pragmatically coded into relevant themes by the same researcher, with oversight and guidance provided by the research team.

Intervention – 'Sleep Ninja'

The Sleep Ninja app was derived from CBT-I and developed by our team, as a fully-automated smartphone app. A participatory design process was used whereby young people contributed to the content, functionality and accessibility/user experience of the app through a series of focus groups [39]. The core strategies included in the app were: psychoeducation, stimulus-control, sleep hygiene and sleep-focused cognitive therapy. Sleep restriction, which aims to increase sleep efficiency by reducing the amount of time spent in bed, was deliberately omitted because some support (parental and/or professional) is likely to be required to successfully implement sleep restriction, particularly in young people. Although sleep restriction did not comprise part of the app, there was instead a focus on the importance or regular sleep-wake cycles. The app teaches users about the importance of consistent sleep and wake times, and recommended bedtimes are calculated based on the time they need to wake up (according to sleep guidelines). This strategy draws from transdiagnostic approaches to target sleep difficulties that go beyond insomnia (e.g., delayed sleep phase and irregular

sleep presentations; [40]) and may therefore be useful to adolescents experiencing a broad range of sleep difficulties.

The structure of the Sleep Ninja app includes six training sessions (lessons), a sleep tracking function, recommended bedtimes based on sleep guidelines, reminders to start a wind-down routine each night, a series of sleep tips, and general information about sleep. The home screen has 3 options: Train, Track, and More (see Figure 1). Users complete training sessions which are delivered through a chat-bot format where the sleep ninja essentially acts as a sleep coach. Training sessions take approximately 5-10 minutes to complete, and cover: (i) psychoeducation, information about circadian rhythms and the importance of keeping regular sleep schedules; (ii) stimulus control, the value of only going to sleep when tired, and strategies that can be used at night when having trouble sleeping; (iii) basic sleep hygiene such as avoiding caffeine and stimulating activity in the evenings, suggestions for daytime activities to promote night-time sleep (e.g., exercise, no napping); (iv)identifying and planning for high-risk situations, how to get back on track after a late-night or sleep in; (v) cognitive therapy including how to deal with unhelpful thoughts that can prevent falling asleep as well as sleep-related cognitive distortions cognitions and; (vi) a final review session which summarises all of the material contained in the app. The user interacts with the app through a forced choice chat-bot format which is responsive to the input of the user, meaning it personalises information and recommendations based on the selections and sleep profile recorded by the participant. Users level up and reach their next "belt" by completing one training session and tracking their sleep for 3 nights (out of a 7-night period). As there were six training sessions to complete, the app was made available for six weeks (42 days) before it locked. Users finish the program with a black belt in sleep.

It is notable that evidence suggests that the use of screens at bedtime interferes with sleep [41]. Drawing on data from large epidemiological studies suggesting that refraining

from screen use for the hour prior to bedtime alleviates potential interference from screens [42], this app has been designed to be used during the day. Users receive a prompt one hour before bed (calculated according to sleep guidelines and their wake-up time) to commence their pre-bed routine and are encouraged to stop using electronic devices after this time. In fact, part of the cognitive component of the app is to educate and challenge beliefs about the importance of night time phone use in order to promote healthy sleep habits. We expect these factors to mitigate the risk that smartphone use in this context will contribute to poor sleep.

Procedure

All procedures were approved by the University of New South Wales Human Research Ethics Committee (HC#16702). Participants were encouraged to download consent forms if they met the eligibility criteria listed on the study website and submit this directly to the research team, once completed. Those who provided written informed consent and that of a parent or guardian were then enrolled in the trial and invited to complete the screening questions to verify study eligibility, before completing baseline questionnaires which included: demographics, ISI, PSQI, PHQ-A, GAD-7 and Expectation of Success. Participants could then access the first day of the online seven-day sleep diary. Another diary entry became available each day for the following six days and participants were reminded to complete entries via text-message. At the completion of seven consecutive entries in the diary, participants were given access to the Sleep Ninja app on their personal smartphone devices. Participants could use the app for six weeks before the post study questionnaire was made available, which included the same battery as baseline with the omission of the Expectations of Success questionnaire and with the addition of the Acceptability and Reasons for Non-Adherence questionnaires. Participants then completed another seven-day sleep diary, which was delivered in the same format and schedule as baseline. After the study had finished, participants were invited to participate in a face-to-face or telephone interview to

provide feedback on their experience of participating in the study. Participants were reimbursed for their time with giftcards to the value of $10 each for completing baseline and post-study assessment schedules; $20 for a telephone interview and $30 for a face-to-face interview.

Participant Involvement and Consultation

Prior to this study, a separate group of young people were consulted in a series of focus groups to inform the design, features and structure of the app (for more information please see [39]). As a feasibility and acceptability study, participants were asked to report on their experiences with respect to both the app and the study procedures, via questionnaires and an in-depth semi-structured interview. Given that a key objective of this study was to assess the acceptability of the Sleep Ninja app, participants' perspectives were of critical importance. A one-page lay summary of the study results has been sent to all participants.

Statistical Analyses

Statistical significance was set at α=.05. Summary scores for sleep diary variables at baseline and post-study were obtained by averaging sleep diary entries at baseline, and averaging sleep diary entries at post-study, respectively. All questionnaire and sleep diary variables were initially screened for excessive skew (>3) or kurtosis (>8; [43]). Six sleep diary variables did not pass screening and were further scrutinised (baseline: WASO entry; post-study: Time fallen asleep, Time in bed after final morning wake up, SOL, TST, SE variables). Examination of these six variables revealed each included an entry that was of an extreme value (*z*-scores ranged from |4.11| to |6.05|) and a decision was made to remove these six values (hence, n = 47 for Baseline WASO; ns = 28 for Post-intervention Time fallen asleep, Time in bed after final morning wake up, SOL, TST, and SE). Subsequently all variables had satisfactory skew and kurtosis.

Questionnaire and sleep diary variables were examined using multilevel modelling. This modelling approach handles missing data by incorporating all available data from each subject into the analysis. Given the aims of our study, our interest centred on the main effect of time (i.e., change from baseline- to post). Random effects were modelled for intercept and time. Models were respecified with a random effect for intercept only in cases where there was no variation in individual baseline- to post-study changes. Within-group effect sizes were computed as the modelled mean difference between baseline and post-study divided by the sample standard deviation at baseline.

Results

Baseline Characteristics

See Table 1 for characteristics of the study sample. Participants had a mean age of 13.71 (*SD*=1.35), were spread across school grade, and nearly all were born in Australia and living in the city. Most participants reported difficulty falling asleep, with about half also reporting problems staying asleep or waking up too early, and about a quarter of the sample were receiving treatment for sleep or a mental health problem.

Table 1. Demographic Variables

Characteristics	Sample (*N* = 50)
Age in years, mean (*SD*, range)	13.71 (1.35, 12-16)
Age in years, n (%)	
12	10 (20.4%)
13	15 (30.6%)
14	7 (14.3%)
15	12 (24.5%)
16	5 (10.2%)
Female, *n* (%)	33 (66%)
Born in Australia, *n* (%)	47 (94%)
Live in the city, *n* (%)	44 (88%)
Sleep problems, *n* (%)	
Difficulty falling asleep	47 (94%)
Difficulty staying asleep	28 (56%)
Problems waking up too early	28 (56%)
Receiving treatment for sleep or mental health problem, *n* (%)	13 (26%)

Note. One participant did not indicate their age, so $n = 49$ for age.

Recruitment Rate

There were more than 300 enquires made to the research team about participation in this trial. Of these, 60 individuals indicated eligibility and returned consent forms. Ten of these participants were not enrolled in the trial; four did not meet inclusion criteria and six withdrew prior to the trial. Reasons for withdrawing were: a change of mind (n=1), a lack of time (n=2), considering participation a chore (n=1), confidentiality concerns (n=1). One participant did not provide a reason. Therefore, 89% (n=50) of the 56 young people who provided consent and met screening criteria continued to trial. See Figure 2 CONSORT diagram for details.

Expectation of Success

Overall, participants were optimistic about using the app, with a mean score of 12.90 (*SD*=2.09) out of a possible 16 points. Every single participant agreed that in principle, people could learn skills for improving sleep from an app, and indicated that they felt that study participation was important. All participants reported that improving their sleep habits were important, with 49% indicating it was 'very important'. Finally, the sample demonstrated their readiness for change with 100% of the sample indicating that they were either moderately ready (16%), ready (43%) or completely ready (41%) to improve their sleep patterns using an app.

Retention

Of the 50 participants in the study sample, 47 (94%) completed the baseline questionnaire and sleep diaries and were invited to download the Sleep Ninja. At post-study, 34 participants completed the post-study battery (72% retention). Participants who had

available data at both time-points did not differ significantly from those who only had baseline data on any of the questionnaires or sleep diary measures (all Fs < 2.58, ps > .115).

Uptake and Adherence

Forty-five participants (96%) who completed the baseline assessment downloaded the Sleep Ninja. Program usage data indicated that of these, 82% completed the first lesson, 51% completed four of the six lessons, and 33% completed all six. Participants were accurate in their reporting of app use, with approximately 80% of participants indicating that they completed 'most' or 'almost all' of the app.

Acceptability

Survey responses on the Acceptability of the Intervention questionnaire indicated that young people reported that the app was 'easy' or 'very easy' to use (97%). The majority of participants (59%) indicated that they learnt 'a fair bit' from the app, and 28% reported that they learnt 'a great deal', while 12% did not learn very much or almost nothing. Participants found the app to be either 'useful' or 'very useful' (78%), while the remainder (22%) did not find it useful. Most respondents (72%) reported changing their behaviour after using the app, and examples of behaviour change included changes to their pre-bedtime routine (22%), keeping more consistent sleep-wake cycles (65%), getting up earlier in the morning (22%), and restricting the use of their bed for sleep (30%). More than half of the participants reported that they would use this kind of app in the future (56%), and encouragingly, 91% would recommend the Sleep Ninja app to a friend. The degree to which participants found the app useful was positively correlated with module completion, (r=.35, p=.047), as was the degree to which participants reported learning from the app (r=.49, p=.004).

The interview mirrored the findings of the questionnaire in terms of acceptability and usefulness. However, there were some aspects of the app that users felt could be improved. Specifically, interviewees expressed a desire for improved explanation of the different app

sections and what they needed to do each time they opened the app. Participants commonly reported wanting to be able to personalise their user experience more, including skipping information they knew, seeking more information around difficult or unfamiliar topics, accessing information in different formats (e.g. video/audio), being able to speed up or slow down the Sleep Ninja's speech, and being able to update their wind-down activity choices and the time the wind-down reminder appeared. Participants expressed a range of views about the tone of the Sleep Ninja, with nearly half of the interviewed participants commenting favourably on the Sleep Ninja's jokes, with several participants commenting that the Sleep Ninja's language was annoying and too childish. There was consensus that the Sleep Ninja's language was repetitive and could be improved by cutting out superfluous dialogue that was not delivering core intervention strategies. Nearly half of the interviewed participants expressed some difficulty in implementing at least one of the Sleep Ninja's recommended strategies due to conflicting parental bedtime rules. For instance, the strategies to delay bedtime until sleepy and leave the bed/bedroom if unable to get to sleep after more than 30 minutes most commonly encountered parental resistance or required modification. Numerous interviewees commented on the usefulness of receiving feedback and summaries of their logged sleep, however several commented that this could be improved by displaying the information in graphs and over time, so that change and improvement is clearer. Overall, participants reported that the number of notifications in the app were acceptable, and that additional reminders should be sent to notify them of available lessons and after periods of inactivity and that these reminders should contain motivational and encouraging messages. While most interviewees considered three nights of sleep tracking per belt acceptable, there were others who felt fewer nights of tracking would have been better, and others who expressed willingness to track more than three nights before levelling up.

Reasons for Non-Adherence

Results from this questionnaire indicated that young people were very happy to use an app to receive help for their sleep issues (84%), did not have technical issues with its use (75%), and felt they had the technical skills to use the app (90%). Participants all reported that the material was relevant and conceptually easy to understand. The main reasons participants reported not using the app was that they felt it took too long to work through (53%), there was too much text to read (47%), and that it was too repetitive (59%).

Preliminary Effects

Sleep and Mental Health Questionnaire Outcomes. Table 2 shows the results for the questionnaire measures. As predicted, from baseline- to post-study, there was a significant decrease in insomnia severity measured by the ISI, β=-4.29, p<.001, d=-0.90, and sleep quality on the PSQI, β=-1.88, p<.001; d=-0.46. Similarly, mental health measures showed a decrease in both depression on the PHQ-A, β=-2.60, p<.001, d=-0.36 and anxiety on the GAD-7, β=-2.56, p<.001, d=-0.41.

Table 2. Questionnaire Measures

	Pre-intervention		*Post-intervention*		*Modelled change from pre- to post-intervention*	
Outcome	*n*	*M (SD)*	*n*	*M (SD)*	*β* [95% CI]	*d*
ISI	50	14.12 (4.75)	34	9.62 (5.23)	-4.29 [-5.63, -2.95]***	-0.90
PSQI	50	10.43 (4.12)	33	8.03 (4.08)	-1.88 [-2.85, -0.90]***	-0.46
PHQ-A	49	13.04 (7.24)	32	9.88 (7.53)	-2.60 [-3.99, -1.22]***	-0.36
GAD-7	49	9.92 (6.19)	32	7.09 (6.13)	-2.56 [-3.59, -1.52]***	-0.41

Note. Raw means (SDs) are presented. Cohen's *d* values are time effects for pre-intervention to post-intervention using the modelled mean difference divided by the sample pre-intervention SD. ISI = Insomnia Severity Index; PSQI = Pittsburgh Sleep Quality Index; PHQ-A = Patient Health Questionnaire modified for Adolescents; GAD-7 = Generalised Anxiety Disorder 7-item.
*** p < .001.

Sleep Diary Outcomes. Results for the sleep diary entries are shown in Table 3. At baseline, participants went to sleep, on average at 11:29pm, reported taking an average of one hour and 12 minutes to fall asleep, spent an average of 9 hours and 39 minutes in bed, woke

up an average of 1.47 times, slept for a total of seven hours and 40 minutes, woke up at 7:27am, and spent approximately 29 minutes awake in bed before getting up. Overall sleep efficiency was just above 80%. Results from the analysis at post-intervention indicated that as predicted, participants went to bed 35 minutes earlier then at baseline (β=-0.58, p=.003), there was a significant decrease of 21 minutes in how long participants took to fall asleep (SOL; β=-0.37, p=.032), participants spent significantly less time in bed after waking than they did at baseline (β=-0.27, p<.001), and woke significantly less frequently during the night reducing to an average of 0.87 times (NWAK; β=-0.46, p=.011). There were also improvements in total sleep time of 33 minutes (TST; β=0.53, p=.005), SE (β=5.25, p=.016), how refreshing sleep was (β=0.43, p<.001) and sleep quality (β=0.31, p=.018). There were no significant differences in the time participants woke up in the morning (on average, at 7:20am), TIB, WASO or medication use (all ps>.05). Within-group Cohen's d effect sizes ranged from small to medium (0.31-0.68).

Table 3. Sleep Diary Measures

	Baseline		*Post-intervention*		*Modelled change from baseline- to post-intervention*	
Outcome	*n*	*M (SD)*	*n*	*M (SD)*	*β* [95% CI]	*d*
Time woken up	48	07:27 (0:46)	29	07:20 (0:54)	-0.10 [-0.41-0.21]	-0.13
Time in bed after final morning wake up (h:min)	48	0:29 (0:23)	28	0:13 (0:10)	-0.27 [-0.41, -0.12]***	**-0.70**
Time fallen asleep	48	23:29 (1:19)	28	22:54 (1:03)	-0.58 [-0.95, -0.21]**	-0.44
TIB (h:min)	48	9:39 (1:11)	29	9:38 (0:55)	-0.01 [-0.42, 0.41]	-0.01
SOL (h:min)	48	1:12 (1:01)	28	0:51 (0:47)	-0.37 [-0.70, -0.03]*	**-0.36**
WASO (h:min)	47	0:14 (0:14)	29	0:12 (0:14)	-0.04 [-0.12, 0.05]	-0.17
TST (h:min)	48	7:40 (1:09)	28	8:13 (1:06)	0.53 [0.17, 0.90]**	**0.46**
NWAK	48	1.47 (1.50)	29	0.87 (1.35)	-0.46 [-0.81, -0.11]*	**-0.31**
SE (%)	48	80.12 (12.01)	28	85.64 (11.30)	5.25 [1.03, 9.47]*	**0.44**
Sleep refreshingness	48	2.37 (0.63)	29	2.78 (0.78)	0.43 [0.19, 0.68]***	**0.68**
Sleep quality	48	2.84 (0.74)	29	3.10 (0.82)	0.31 [0.06, 0.56]*	**0.42**
Use of medication	48	0.12 (0.30)	29	0.11 (0.30)	-0.01 [-0.02, 0.01]	-0.03

Note. Raw means (SDs) are presented. Cohen's *d* values are time effects for pre-intervention to post-intervention using the modelled mean difference divided by the sample pre-intervention SD. Time fallen asleep and Time woken up are expressed as times in 24-hour time. Time variables (TIB, SOL, WASO, TST) are expressed in hours:minutes. TIB = Time in bed; SOL = Sleep onset latency; WASO = Wake after sleep onset; TST = Total sleep time; NWAK = Number of awakenings; SE = Sleep efficiency.SE is expressed as a percentage. Refreshingness of sleep is rated on a Likert scale from 1 = *Exhausted* to 5 = *Very refreshed.* Quality of sleep is rated on a Likert scale from 1 = *Very Poor* to 5 = *Very Good*. Use of medication is expressed as a proportion of days medication was used to help with sleep.
* $p < .05$, ** $p < .01$, *** $p < .001$.

Discussion

The purpose of this pilot study was to evaluate the feasibility, acceptability and preliminary effects of the Sleep Ninja app on sleep and mental health symptoms, for use among adolescents with sleep difficulties. A secondary objective of the study was to gather information in order to refine aspects of the app before evaluating it in a larger trial. Our findings confirmed that young people with sleep difficulties were optimistic about using the app and could complete baseline questionnaires and sleep diaries using an automated digital format without assistance. Feasibility was confirmed based on uptake, completion and retention rates with young people volunteering for the study, downloading the app and completing most of the lessons. This provides evidence that the Sleep Ninja app is a feasible intervention to deliver to young people experiencing sleep difficulties.

Intervention adherence levels suggested that while more than half of the participants completed more than half of the app, only one third of participants completed all six lessons. While this is within the range of adherence rates reported in the literature for technology-mediated insomnia programs [44], reasons for non-adherence require consideration as there is room for improvement. The main reason participants had difficulty or stopped using the app was reportedly due to the amount of text presented in the app and the repetitive nature of the material. Participants also requested a more tailored experience. Those who completed more of the app also reported it to be more acceptable. Therefore, it is likely that refining the app by taking these points into account is likely to increase engagement with the content and overall adherence to the intervention.

Efficacy outcomes showed that insomnia symptoms improved significantly from baseline to post-study, effectively moving participants from the lower cut off for clinical insomnia, firmly into the sub-threshold symptom level. There was an improvement in self-reported sleep quality, with a medium effect size (d=-0.46) suggesting app use improves

quality of sleep. The improvements detected on the two sleep questionnaire measures (ISI, PQSI) were corroborated by those found in the sleep diaries, with participants going to bed earlier, falling asleep more quickly at night, waking less frequency, sleeping for longer, spending less time in bed in the morning after waking, and reporting improved sleep efficiency and quality.

The time that participants reported waking each morning did not shift. This finding needs to be considered in the context of young people having to get up at a specific time for school each morning. School start times are a modifiable contributing factor to insufficient sleep, with evidence suggesting that delaying school start times by even 30 minutes is associated with higher levels of school attendance, lower daytime sleepiness, and improved attention and concentration [45]. While there have been calls to delay school start times to improve sleep duration, health and functioning (e.g., [46]), this is unlikely to change in the Australian context. Accordingly, a focus on bed times rather than rise times is likely to be most useful for treating sleep difficulties in this age group, at least for the time being.

Findings on these sleep outcomes are consistent with the two studies which have evaluated web-delivered CBT-I for adolescents with insomnia [15, 16, 17), and show for the first time that CBT-I, when delivered to adolescents by smartphone-app, confer benefits. It is encouraging that the within-group effect size obtained in the current study for insomnia (d=-0.90) is comparable to within-group effect size found for digitally-delivered CBT-I in a randomised trial (d=-0.92; [16]). In this randomised study, the intervention group was found to be superior to the waitlist control, suggesting that a within-group effect size of this magnitude is likely to reflect improvement over and above what would be expected based on a standard placebo effect [16].

Beyond the sleep outcomes, we also found that there were decreases in depression and anxiety symptoms following the completion of the intervention suggesting that there may be

value in using this app to address mental illness. The magnitude of the decrease in depression scores is notable, with individuals moving from the moderate range into the mild range, and a within-group effect size that is comparable to other adolescent depression prevention trials [47]. These findings provide proof-of-principle evidence that the Sleep Ninja app may be useful in addressing depression. As a pilot study, we did not test the specific hypothesis that targeting insomnia will decrease depression risk. Given our encouraging findings, a follow-up randomised controlled trial which follows participants over time, which can determine causality between insomnia and depression, that can assess the mechanisms of change, as well as the impact of intervention on depression risk is now warranted.

This study makes a unique contribution to the literature by showing that smartphone delivery of CBT-I is a promising format in which to deliver this gold-standard intervention. This is the first study that we are aware of that has evaluated app-delivered CBT-I in young people [21], and only the second study that has tested mobile phone delivery of CBT-I, the first study being conducted in adults, with positive effects on sleep outcomes [48]. Using smartphones to deliver interventions such as this offer a myriad of advantages, including immediate connectivity to automated interactive applications that can be accessed anytime, anywhere. Sleep Ninja has been developed so that it does not rely on internet access for use, which is likely to be important to young people who may have limited data plans, and individuals who do not have optimal internet coverage. Not requiring internet coverage to access digital programs represents a new wave of flexibility in the delivery of health interventions and the automated nature of the intervention means it can be delivered without professional support. It is notable that we had a 72% retention rate, which is at the upper level of that detected for digital interventions which has been shown in a meta-analysis to range between 43-99% [49], with retention rates typically lower in non-supported interventions [50].

There are several study limitations that need to be considered. First, participants in this trial were required to have relatively minor levels of insomnia symptoms for study entry. This decision was made by balancing inclusiveness against the requirement of sleep disturbance to ensure participants were motivated to use the app. Moreover, given the study focus was on feasibility and acceptability, we felt it would be prudent to establish these factors before targeting a more severe participant group. That said, while we set the threshold for entry relatively low, both the mean and the median converged on an ISI score of just above 14, indicating that participants were at the junction between having subthreshold and clinical levels of insomnia symptoms (cut-off score is 15). Therefore, it is relatively unlikely that there would have been a floor effect as the data showed there was sufficient room to detect symptom-improvement. The high mean symptom level also suggests that the results may generalise to a group with clinical levels of insomnia. Second, we did not include a control group. Again, as the study goal was to establish feasibility and acceptability, it was not necessary to include a control group for this purpose. However, this design is not able to attribute causality to the intervention and a controlled study is now needed. Finally, this study relied exclusively on subjectively reported sleep outcomes. Although objective measures such as polysomnography provide the most accurate way to assess sleep, there is evidence that subjectively measured sleep variables could be more closely associated with functional outcomes [51]. Moreover, subjectively experienced sleep quality and parameters have consistently shown to be strongly associated with psychological wellbeing [52, 53], suggesting that perception of sleep is as important, if not more so, than objective measures. We are currently investigating how inbuilt smartphone sensors such as the accelerometer might be used to provide a more objective estimate of sleep.

This study provides preliminary evidence supporting the feasibility, acceptability and effects of a fully-automated app that targets adolescent sleep difficulties. The Sleep Ninja

intervention shows promise both as a sleep-focused intervention, but also potentially to reduce risk for depression.

Figure Legends

Figure 1. Example screens from the Sleep Ninja app. From left: Homescreen, Training Session Access and Progress Record, Tracking and Bedtime Setting, More Information

Figure 2. Participant Flow

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Author Statement

AW-S, BO, MT and HC conceived of the study and the trial design. AW-S designed the study with input from all authors, and oversaw the management of the trial. LJ led trial recruitment, managed the day-to-day running of the trial and conducted the participant interviews. QW conducted the analyses with assistance from AW-S and LJ. All authors contributed to the preparation of the manuscript.

Competing Interests Statement

No competing interests to declare.

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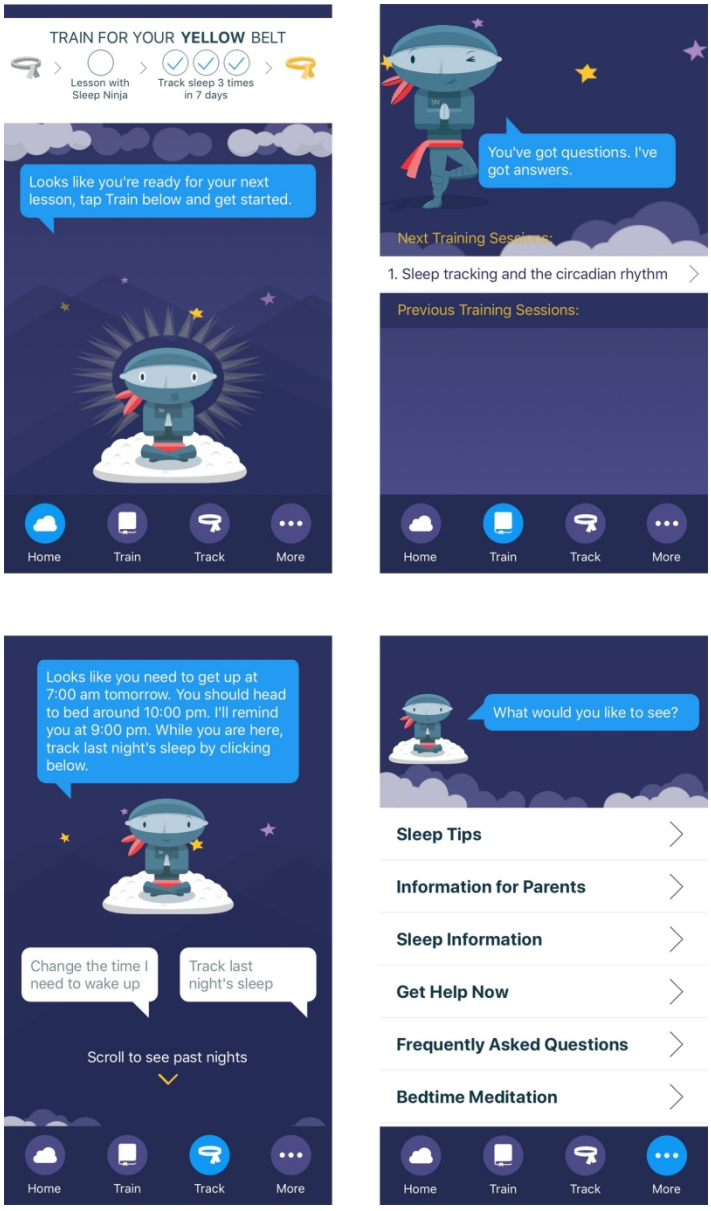

Figure 1. Example screens from the Sleep Ninja app. From left: Homescreen, Training Session Access and Progress Record, Tracking and Bedtime Setting, More Information

139x238mm (300 x 300 DPI)

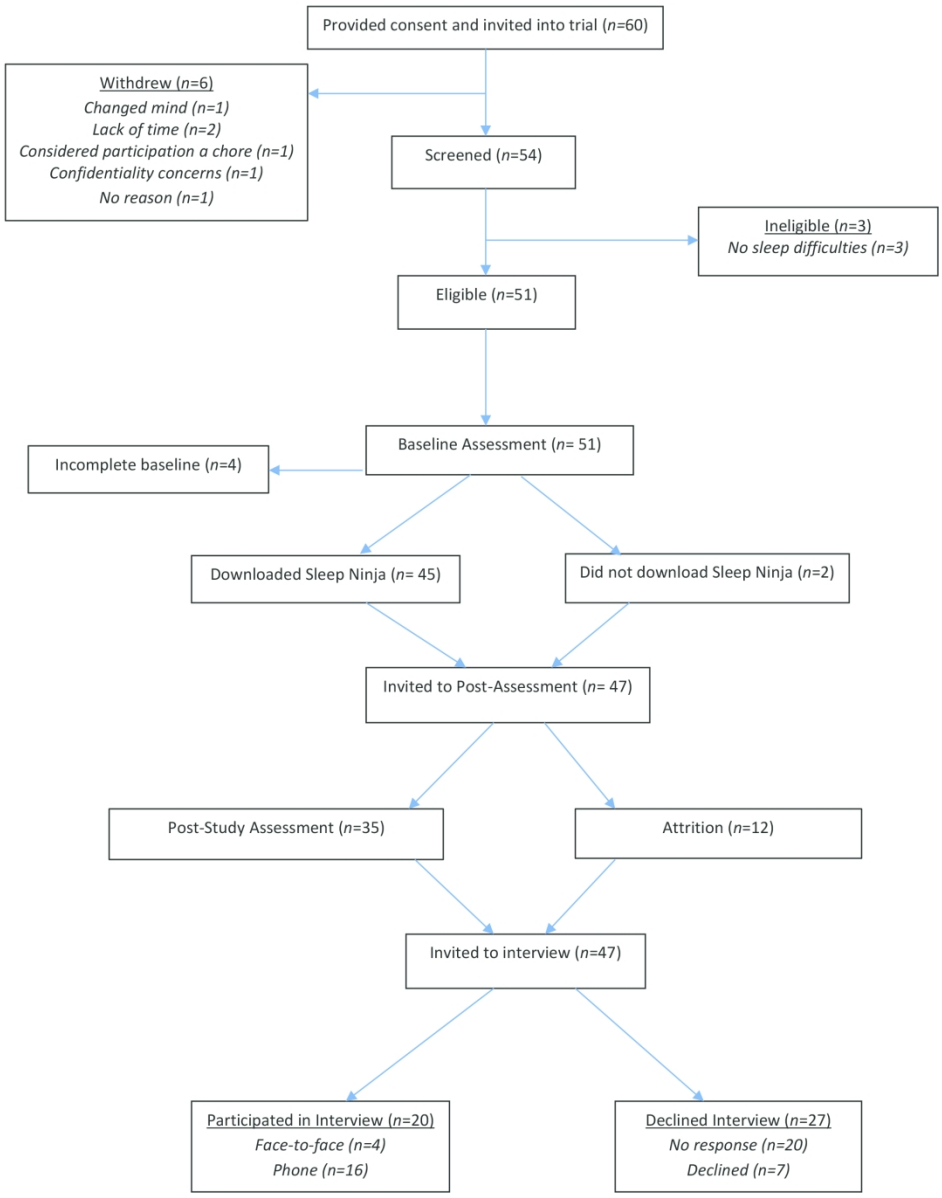

Figure 2. Participant Flow

187x238mm (300 x 300 DPI)

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A pilot evaluation of the Sleep Ninja – a smartphone-application for adolescent insomnia symptoms

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A pilot evaluation of the Sleep Ninja – a smartphone-application for adolescent insomnia symptoms

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Abstract

Objectives: The aim of this study was to test the feasibility, acceptability and preliminary effects of a recently developed smartphone application, Sleep Ninja, for adolescent sleep difficulties.

Setting: The study was conducted online with Australian individuals recruited through the community.

Participants: Participants were 50 young people aged 12-16 years with sleep difficulties.

Design: A single-arm pre-post design was used to evaluate feasibility, acceptability and sleep and mental health variables at baseline and post-intervention.

Intervention: Cognitive Behaviour Therapy for Insomnia (CBT-I) informed the development of the Sleep Ninja. The core strategies covered by the app are psychoeducation, stimulus-control, sleep hygiene, and sleep-related cognitive therapy. It includes six training sessions (lessons), a sleep tracking function, recommended bedtimes based on sleep guidelines, reminders to start a wind-down routine each night, a series of sleep tips, and general information about sleep. Users progress through each training session and conclude the six-week program with a black belt in sleep.

Outcome measures: Feasibility was evaluated based on consent rates, adherence and attrition, acceptability was assessed using questionnaires and a post-study interview, and sleep, depression and anxiety variables were assessed at baseline and post-intervention.

Results: Data indicated that the Sleep Ninja is a feasible intervention and is acceptable to young people. Findings showed there were significant improvements on sleep variables including insomnia (within-group effect size d=-0.90), sleep quality (d=-0.46), depression (d=-0.36) and anxiety (d=-0.41).

Conclusions: The Sleep Ninja is a promising intervention that could assist adolescents who experience sleep difficulties. A follow-up randomised controlled trial is now warranted.

Trial registration: Australian New Zealand Clinical Trials Registry (#ACTRN12617000141347).

Article Summary

Strengths and limitations of this study

- This is the first study to evaluate app-delivered Cognitive Behavioural Therapy for Insomnia in adolescents with sleep difficulties.
- The intervention being tested, Sleep Ninja, was developed with input from young people, is fully automated and does not require internet coverage to function.
- The evaluation included measures of feasibility and acceptability as well as detailed semi-structured interviews about participants' experience with the app.
- As a preliminary study, this study did not include a control group.

Clinical insomnia is a sleep disturbance characterised by difficulty falling asleep, staying asleep or waking up too early, with associated daytime impairment [1]. It effects approximately 4% of adolescents [2], however sub-threshold symptoms are common, with approximately 25% of young people reporting some degree of sleep disturbance [2, 3].

Depression and insomnia are closely linked, with comorbidity levels as high as 73% in young people [4]. Insomnia is not only a symptom of depression, but is a common precursor, with high quality longitudinal data having established insomnia as an independent risk factor for depression onset [5, 6, 7]. For example, a recent meta-analysis found that insomnia was associated with a greater than two-fold increase in depression risk [5]. Although depression has multiple causes and maintaining factors that go beyond the presence of sleep problems, the literature suggests that sleep plays an important role, and targeting sleep in the context of depression may have wide-reaching benefits [6].

There is emerging evidence that addressing insomnia in individuals with concurrent insomnia and depression improves both sleep and depression outcomes [8, 9, 10]. This suggests there may be value in targeting sleep to improve insomnia symptoms, with potential downstream effects on depression. To our knowledge, there have been three studies testing the hypothesis that targeting insomnia can prevent depressive symptoms. In an adult study, insomnia treatment led to a reduction in depression following the intervention and at 6 and 18-month follow-up, relative to an active control group [11, 12]. In a youth study, a face-to-face insomnia intervention was delivered to secondary school students and results showed improvements on sleep and anxiety outcomes, but not symptoms of depression [13]. Data from the two-year follow-up from this study has not yet been published [14]. In a second youth study, a sleep intervention delivered either in group format or digitally led to decreased depressive symptoms at both 2 and 12-month follow-up, an effect that was mediated by improvements in insomnia [15].

The gold standard treatment for insomnia is cognitive behaviour therapy for insomnia (CBT-I; Australasian Sleep Association, American College of Physicians), and there is accumulating evidence to support the use of digitally delivered CBT-I in both adults and young people [16, 17, 18, 19]. Delivering sleep interventions via digital formats may be particularly well-suited to young people, with adolescents showing a strong preference (97%) for digital delivery when given the choice between face-to-face and digital CBT-I [17]. This preference may in part be explained by the fact that young people are reluctant to seek help for psychological issues, for reasons that include stigma and a preference to manage the problem themselves [20]. Sleep is typically less stigmatised than disorders like depression, suggesting that it may be more appealing to adolescents. Currently, there are no digital CBT-I programs that are commercially available for youth [21]. To overall objective of this study was to evaluate a newly-developed digital CBT-I program for adolescents with sleep difficulties.

The aim of this pilot study was to examine the acceptability, feasibility and preliminary effects of an intervention (Sleep Ninja) delivered to adolescents via smartphones. In line with the guidelines on the development of behavioural interventions [22, 23], the primary purpose of this study was to investigate recruitment rates, uptake, intervention completion, reasons for non-adherence, and participant retention. The secondary aim was to use both quantitative and qualitative methods to determine the acceptability of the app among young people with sleep difficulties and allow for the refinement of the intervention prior to a formal randomised evaluation. A final aim was to examine the impact of the Sleep Ninja app on sleep outcomes and mental health symptoms. We used a single-arm, pre-post design to address these aims. It was hypothesised that the app would be a feasible modality in which to deliver the automated sleep intervention, as measured by uptake, completion and retention

rates, that the app would be acceptable to young people, and that its use would be associated with improvement in sleep and mental health symptoms.

Method

This trial was prospectively registered on the Australian New Zealand Clinical Trials Registry (#ACTRN12617000141347).

Participants

Fifty participants were recruited via media and social media channels, including the Black Dog Institute's website and paid Facebook advertisements that targeted potential participants and their parents between April-June, 2017. A sample size of 50 was selected in order to successfully meet the study's feasibility and acceptability aims. Inclusion criteria were: aged 12-16 years, presence of at least mild insomnia, operationalised by endorsement of at least one of the following symptoms over the preceding two-week period: difficulty falling asleep, difficulty staying asleep or waking up too early. These items are the first three questions on the Insomnia Severity Index [24], and were chosen to include a participant group with at least mild levels of insomnia. For study inclusion, participants also needed to own a smartphone running iOS or Android, have a valid email address, access to the internet, and be able to provide personal and parental consent.

Measures

Insomnia Severity Index (ISI). The ISI is a psychometrically sound, seven-item self-report measure of insomnia symptoms over the previous two weeks [24, 25]. Responses are reported on a Likert scale from 0 to 4, producing total scores of 0 to 28 [24, 25]. Cut-off scores are as follows: 0-7 reflects no clinically significant insomnia, 8-14 indicates subthreshold insomnia, 15-21 suggests moderate severity insomnia, and 22-28 indicates

severe insomnia [24]. The ISI was designed for use in adults but has been widely administered to, and validated in, adolescent samples [25, 26, 27]. In one adolescent validation study, reliability was strong (Cronbach's α=0.83), and test-retest reliability was acceptable, *r*=.79 [25].

Pittsburgh Sleep Quality Index (PSQI). The PSQI is a widely used self-report 19-item scale that assesses usual sleep habits and experiences over the preceding month and has been validated in adolescent samples, with strong internal consistency (α=.72) and test-retest reliability over a 6-week period (*r*=.81) [28]. There are seven sub-scales which are sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medications, daytime dysfunction [29]. Each component is scored from 0 (no difficulty) to 3 (severe difficulty), which are summed to obtain a Global PSQI score ranging from 0 to 21 [30].

Patient Health Questionnaire – Adolescent Version (PHQ-A). The PHQ-A assesses depressive symptoms in the preceding two weeks in adolescents, and has been adapted from the widely used PHQ-9 designed for adults [31]. This measure has excellent psychometric properties, including α= 0.89, and test-retest reliability of *r*=0.84 [32]. In this study, we used the 8-item version in which the questions are identical to those asked in the PHQ-9 with the exclusion of the last item which asks about suicide and is comparable to the PHQ-9 in terms of diagnosing depressive disorders [32, 33]. Each item is scored on a 4-point scale and summed together to form a total depression score ranging from 0 to 24. Scores correspond to the following cut-offs: 0-9 indicates minimal symptoms, 10-14 indicates mild symptoms, 15-19 reflects moderate symptoms, and 20-24 is indicative of severe depression [31]. The PHQ-A has demonstrated good sensitivity (73%) and high specificity (94%) for major depressive disorder [31].

Generalised Anxiety Disorder 7-item (GAD-7). The GAD-7 evaluates symptoms of generalised anxiety disorder [34]. All items are scored on a scale from 0 (not at all) to 3 (nearly every day). The scores on each item are summed together to derive a total score, ranging from 0 to 21 of which 0-4 indicates minimal anxiety, 5-9 mild anxiety, 10-14 moderate anxiety, and 15-21 severe anxiety [34]. The GAD-7 has good sensitivity (89%) and specificity (82%) for GAD scores >10 [34]. The measure has also been validated in adolescent populations with Cronbach's α=0.90 and high convergent and discriminant validity [35].

Expectations of Success. A four-item scale was developed for this study to assess participants' motivation and expectations for improving their sleep with an app (e.g., *I am confident that people could learn skills for improving sleep from an app*). The four items assessed perceived confidence, importance, usefulness and readiness to change. The Expectation of Success measure was scored on a five-point scale and total scores were computed by summing each item, ranging from 0 to 16. Higher scores on this scale indicate greater confidence and readiness to target sleep using a smartphone app.

Acceptability of the Intervention. The Acceptability of the Intervention scale is a seven-item measure that was developed by the research team to assess participants' attitudes and behaviours associated with using the app (e.g., *How much did you learn from the app* and *Would you recommend this program to others?)*. This measure was informed by similar acceptability measures commonly used in the field [36]. Each item was designed to assess a different domain. The first four domains to be assessed were app completion, ease of use, amount learnt and usefulness, with each being scored on an ordinal scale from 0-3. The final three items assessed behaviour change, whether the participant would use an app like this in the future, and whether they would recommend it to a friend, and were scored dichotomously as either yes or no, with an option for participants to describe the nature of their behaviour

change if yes. As each question assessed a different domain, item scores were considered separately.

Reasons for Non-Adherence. The Reasons for Non-Adherence measure is a 23-item scale that was adapted from a previous measure [37] to assess the degree to which different reasons impacted on participants' use of the app. There are four domains assessed: phone/internet/technical issues *(e.g., My phone wasn't working or was having problems);* personal issues *(e.g., I didn't think I deserved help);* intervention-general issues *(e.g., I wasn't convinced the app would be helpful);* and intervention-specific issues *(e.g., There was too much text to read).* Participants responded on an ordinal scale indicating whether each item played no, a little or major part in why they stopped or had difficulty using the app as intended. The scores on each item were considered separately.

Sleep Diary. The ten-item Sleep Diary was developed by the research team incorporating the questions from the Consensus Sleep Diary [38], with the addition of two questions regarding daytime naps and use of sleep medication. Participants answered 10 questions which included bedtime, time taken to fall asleep (sleep onset latency; SOL), number and duration of night-time awakenings (number of awakenings; NWAK, duration of wakefulness after sleep onset; WASO), time of final awakening, time participants got out of bed for the day, subjective sleep quality, how refreshed participants felt upon awakening, duration of any daytime naps and use of sleep medication. Sleep diaries were completed electronically with pre-set categories from which users selected responses from a drop-down menu. A clock scroller was used to enter the time and/or duration of all sleep-related activities and all times were entered in 12-hour format to minimise errors associated with 24-hour time. Restrictions were set to ensure participants could not enter a wake time earlier than bedtime and visa versa. All questions required answers for the sleep diary to be submitted. From the sleep diary we calculated time between waking in the morning and getting out of

bed, time in bed (TIB), total sleep time (TST; calculated by subtracting SOL, WASO and time between waking and getting up in the morning, from TIB) and sleep efficiency (SE; calculated by taking the percentage of TST/TIB).

Post-Study Interview. After study completion, participants were invited to attend a face-to-face or telephone interview to provide feedback on their experience. Interviews were semi-structured and explored participants' opinions about the study in general, and specifically in relation to the intervention. Questions were open-ended, and flexible enough to explore ideas that were raised during each interview. Interviews were audio recorded and then transcribed verbatim by the interviewer. The interview content was pragmatically coded into relevant themes by the same researcher, with oversight and guidance provided by the research team.

Intervention – 'Sleep Ninja'

The Sleep Ninja app was derived from CBT-I and developed by our team, as a fully-automated smartphone app. A participatory design process was used whereby young people contributed to the content, functionality and accessibility/user experience of the app through a series of focus groups [39]. The core strategies included in the app were: psychoeducation, stimulus-control, sleep hygiene and sleep-focused cognitive therapy. Sleep restriction, which aims to increase sleep efficiency by reducing the amount of time spent in bed, was deliberately omitted because some support (parental and/or professional) is likely to be required to successfully implement sleep restriction, particularly in young people. Although sleep restriction did not comprise part of the app, there was instead a focus on the importance or regular sleep-wake cycles. The app teaches users about the importance of consistent sleep and wake times, and recommended bedtimes are calculated based on the time they need to wake up (according to sleep guidelines). This strategy draws from transdiagnostic approaches to target sleep difficulties that go beyond insomnia (e.g., delayed sleep phase and irregular

sleep presentations; [40]) and may therefore be useful to adolescents experiencing a broad range of sleep difficulties.

The structure of the Sleep Ninja app includes six training sessions (lessons), a sleep tracking function, recommended bedtimes based on sleep guidelines, reminders to start a wind-down routine each night, a series of sleep tips, and general information about sleep. The home screen has 3 options: Train, Track, and More (see Figure 1). Users complete training sessions which are delivered through a chat-bot format where the sleep ninja essentially acts as a sleep coach. Training sessions take approximately 5-10 minutes to complete, and cover: (i) psychoeducation, information about circadian rhythms and the importance of keeping regular sleep schedules; (ii) stimulus control, the value of only going to sleep when tired, and strategies that can be used at night when having trouble sleeping; (iii) basic sleep hygiene such as avoiding caffeine and stimulating activity in the evenings, suggestions for daytime activities to promote night-time sleep (e.g., exercise, no napping); (iv)identifying and planning for high-risk situations, how to get back on track after a late-night or sleep in; (v) cognitive therapy including how to deal with unhelpful thoughts that can prevent falling asleep as well as sleep-related cognitive distortions cognitions and; (vi) a final review session which summarises all of the material contained in the app. The user interacts with the app through a forced choice chat-bot format which is responsive to the input of the user, meaning it personalises information and recommendations based on the selections and sleep profile recorded by the participant. Users level up and reach their next "belt" by completing one training session and tracking their sleep for 3 nights (out of a 7-night period). As there were six training sessions to complete, the app was made available for six weeks (42 days) before it locked. Users finish the program with a black belt in sleep.

It is notable that evidence suggests that the use of screens at bedtime interferes with sleep [41]. Drawing on data from large epidemiological studies suggesting that refraining

from screen use for the hour prior to bedtime alleviates potential interference from screens [42], this app has been designed to be used during the day. Users receive a prompt one hour before bed (calculated according to sleep guidelines and their wake-up time) to commence their pre-bed routine and are encouraged to stop using electronic devices after this time. In fact, part of the cognitive component of the app is to educate and challenge beliefs about the importance of night time phone use in order to promote healthy sleep habits. We expect these factors to mitigate the risk that smartphone use in this context will contribute to poor sleep.

Procedure

All procedures were approved by the University of New South Wales Human Research Ethics Committee (HC#16702). Participants were encouraged to download consent forms if they met the eligibility criteria listed on the study website and submit this directly to the research team, once completed. Those who provided written informed consent and that of a parent or guardian were then enrolled in the trial and invited to complete the screening questions to verify study eligibility, before completing baseline questionnaires which included: demographics, ISI, PSQI, PHQ-A, GAD-7 and Expectation of Success. Participants could then access the first day of the online seven-day sleep diary. Another diary entry became available each day for the following six days and participants were reminded to complete entries via text-message. At the completion of seven consecutive entries in the diary, participants were given access to the Sleep Ninja app on their personal smartphone devices. Participants could use the app for six weeks before the post study questionnaire was made available, which included the same battery as baseline with the omission of the Expectations of Success questionnaire and with the addition of the Acceptability and Reasons for Non-Adherence questionnaires. Participants then completed another seven-day sleep diary, which was delivered in the same format and schedule as baseline. After the study had finished, participants were invited to participate in a face-to-face or telephone interview to

provide feedback on their experience of participating in the study. Participants were reimbursed for their time with giftcards to the value of $10 each for completing baseline and post-study assessment schedules; $20 for a telephone interview and $30 for a face-to-face interview.

Participant Involvement and Consultation

Prior to this study, a separate group of young people were consulted in a series of focus groups to inform the design, features and structure of the app (for more information please see [39]). As a feasibility and acceptability study, participants were asked to report on their experiences with respect to both the app and the study procedures, via questionnaires and an in-depth semi-structured interview. Given that a key objective of this study was to assess the acceptability of the Sleep Ninja app, participants' perspectives were of critical importance. A one-page lay summary of the study results has been sent to all participants.

Statistical Analyses

Statistical significance was set at α=.05. Summary scores for sleep diary variables at baseline and post-study were obtained by averaging sleep diary entries at baseline, and averaging sleep diary entries at post-study, respectively. All questionnaire and sleep diary variables were initially screened for excessive skew (>3) or kurtosis (>8; [43]). Six sleep diary variables did not pass screening and were further scrutinised (baseline: WASO entry; post-study: Time fallen asleep, Time in bed after final morning wake up, SOL, TST, SE variables). Examination of these six variables revealed each included an entry that was of an extreme value (*z*-scores ranged from |4.11| to |6.05|) and a decision was made to remove these six values (hence, n = 47 for Baseline WASO; ns = 28 for Post-intervention Time fallen asleep, Time in bed after final morning wake up, SOL, TST, and SE). Subsequently all variables had satisfactory skew and kurtosis.

Questionnaire and sleep diary variables were examined using multilevel modelling. This modelling approach handles missing data by incorporating all available data from each subject into the analysis. Given the aims of our study, our interest centred on the main effect of time (i.e., change from baseline- to post). Random effects were modelled for intercept and time. Models were respecified with a random effect for intercept only in cases where there was no variation in individual baseline- to post-study changes. Within-group effect sizes were computed as the modelled mean difference between baseline and post-study divided by the sample standard deviation at baseline.

Results

Baseline Characteristics

See Table 1 for characteristics of the study sample. Participants had a mean age of 13.71 (*SD*=1.35), were spread across school grade, and nearly all were born in Australia and living in the city. Most participants reported difficulty falling asleep, with about half also reporting problems staying asleep or waking up too early, and about a quarter of the sample were receiving treatment for sleep or a mental health problem.

Table 1. Demographic Variables

Characteristics	Sample (*N* = 50)
Age in years, mean (*SD*, range)	13.71 (1.35, 12-16)
Age in years, n (%)	
12	10 (20.4%)
13	15 (30.6%)
14	7 (14.3%)
15	12 (24.5%)
16	5 (10.2%)
Female, *n* (%)	33 (66%)
Born in Australia, *n* (%)	47 (94%)
Live in the city, *n* (%)	44 (88%)
Sleep problems, *n* (%)	
Difficulty falling asleep	47 (94%)
Difficulty staying asleep	28 (56%)
Problems waking up too early	28 (56%)
Receiving treatment for sleep or mental health problem, *n* (%)	13 (26%)

Note. One participant did not indicate their age, so $n = 49$ for age.

Recruitment Rate

There were more than 300 enquires made to the research team about participation in this trial. Of these, 60 individuals indicated eligibility and returned consent forms. Ten of these participants were not enrolled in the trial; four did not meet inclusion criteria and six withdrew prior to the trial. Reasons for withdrawing were: a change of mind (n=1), a lack of time (n=2), considering participation a chore (n=1), confidentiality concerns (n=1). One participant did not provide a reason. Therefore, 89% (n=50) of the 56 young people who provided consent and met screening criteria continued to trial. See Figure 2 CONSORT diagram for details.

Expectation of Success

Overall, participants were optimistic about using the app, with a mean score of 12.90 (*SD*=2.09) out of a possible 16 points. Every single participant agreed that in principle, people could learn skills for improving sleep from an app, and indicated that they felt that study participation was important. All participants reported that improving their sleep habits were important, with 49% indicating it was 'very important'. Finally, the sample demonstrated their readiness for change with 100% of the sample indicating that they were either moderately ready (16%), ready (43%) or completely ready (41%) to improve their sleep patterns using an app.

Retention

Of the 50 participants in the study sample, 47 (94%) completed the baseline questionnaire and sleep diaries and were invited to download the Sleep Ninja. At post-study, 34 participants completed the post-study battery (72% retention). Participants who had available data at both time-points did not differ significantly from those who only had baseline data on any of the questionnaires or sleep diary measures (all Fs < 2.58, ps > .115).

Uptake and Adherence

Forty-five participants (96%) who completed the baseline assessment downloaded the Sleep Ninja. Program usage data indicated that of these, 82% completed the first lesson, 51% completed four of the six lessons, and 33% completed all six. Participants were accurate in their reporting of app use, with approximately 80% of participants indicating that they completed 'most' or 'almost all' of the app.

Acceptability

Survey responses on the Acceptability of the Intervention questionnaire indicated that young people reported that the app was 'easy' or 'very easy' to use (97%). The majority of participants (59%) indicated that they learnt 'a fair bit' from the app, and 28% reported that they learnt 'a great deal', while 12% did not learn very much or almost nothing. Participants found the app to be either 'useful' or 'very useful' (78%), while the remainder (22%) did not find it useful. Most respondents (72%) reported changing their behaviour after using the app, and examples of behaviour change included changes to their pre-bedtime routine (22%), keeping more consistent sleep-wake cycles (65%), getting up earlier in the morning (22%), and restricting the use of their bed for sleep (30%). More than half of the participants reported that they would use this kind of app in the future (56%), and encouragingly, 91% would recommend the Sleep Ninja app to a friend. The degree to which participants found the app useful was positively correlated with module completion, (r=.35, p=.047), as was the degree to which participants reported learning from the app (r=.49, p=.004).

The interview mirrored the findings of the questionnaire in terms of acceptability and usefulness. However, there were some aspects of the app that users felt could be improved. Specifically, interviewees expressed a desire for improved explanation of the different app sections and what they needed to do each time they opened the app. Participants commonly reported wanting to be able to personalise their user experience more, including skipping

information they knew, seeking more information around difficult or unfamiliar topics, accessing information in different formats (e.g. video/audio), being able to speed up or slow down the Sleep Ninja's speech, and being able to update their wind-down activity choices and the time the wind-down reminder appeared. Participants expressed a range of views about the tone of the Sleep Ninja, with nearly half of the interviewed participants commenting favourably on the Sleep Ninja's jokes, with several participants commenting that the Sleep Ninja's language was annoying and too childish. There was consensus that the Sleep Ninja's language was repetitive and could be improved by cutting out superfluous dialogue that was not delivering core intervention strategies. Nearly half of the interviewed participants expressed some difficulty in implementing at least one of the Sleep Ninja's recommended strategies due to conflicting parental bedtime rules. For instance, the strategies to delay bedtime until sleepy and leave the bed/bedroom if unable to get to sleep after more than 30 minutes most commonly encountered parental resistance or required modification. Numerous interviewees commented on the usefulness of receiving feedback and summaries of their logged sleep, however several commented that this could be improved by displaying the information in graphs and over time, so that change and improvement is clearer. Overall, participants reported that the number of notifications in the app were acceptable, and that additional reminders should be sent to notify them of available lessons and after periods of inactivity and that these reminders should contain motivational and encouraging messages. While most interviewees considered three nights of sleep tracking per belt acceptable, there were others who felt fewer nights of tracking would have been better, and others who expressed willingness to track more than three nights before levelling up.

Reasons for Non-Adherence

Results from this questionnaire indicated that young people were very happy to use an app to receive help for their sleep issues (84%), did not have technical issues with its use (75%), and felt they had the technical skills to use the app (90%). Participants all reported that the material was relevant and conceptually easy to understand. The main reasons participants reported not using the app was that they felt it took too long to work through (53%), there was too much text to read (47%), and that it was too repetitive (59%).

Preliminary Effects

Sleep and Mental Health Questionnaire Outcomes. Table 2 shows the results for the questionnaire measures. As predicted, from baseline- to post-study, there was a significant decrease in insomnia severity measured by the ISI, β=-4.29, p<.001, d=-0.90, and sleep quality on the PSQI, β=-1.88, p<.001; d=-0.46. Similarly, mental health measures showed a decrease in both depression on the PHQ-A, β=-2.60, p<.001, d=-0.36 and anxiety on the GAD-7, β=-2.56, p<.001, d=-0.41.

Table 2. Questionnaire Measures

	Pre-intervention		*Post-intervention*		*Modelled change from pre- to post-intervention*	
Outcome	*n*	*M (SD)*	*n*	*M (SD)*	*β* [95% CI]	*d*
ISI	50	14.12 (4.75)	34	9.62 (5.23)	-4.29 [-5.63, -2.95]***	-0.90
PSQI	50	10.43 (4.12)	33	8.03 (4.08)	-1.88 [-2.85, -0.90]***	-0.46
PHQ-A	49	13.04 (7.24)	32	9.88 (7.53)	-2.60 [-3.99, -1.22]***	-0.36
GAD-7	49	9.92 (6.19)	32	7.09 (6.13)	-2.56 [-3.59, -1.52]***	-0.41

Note. Raw means (SDs) are presented. Cohen's *d* values are time effects for pre-intervention to post-intervention using the modelled mean difference divided by the sample pre-intervention SD. ISI = Insomnia Severity Index; PSQI = Pittsburgh Sleep Quality Index; PHQ-A = Patient Health Questionnaire modified for Adolescents; GAD-7 = Generalised Anxiety Disorder 7-item.
*** p < .001.

Sleep Diary Outcomes. Results for the sleep diary entries are shown in Table 3. At baseline, participants went to sleep, on average at 11:29pm, reported taking an average of one hour and 12 minutes to fall asleep, spent an average of 9 hours and 39 minutes in bed, woke

up an average of 1.47 times, slept for a total of seven hours and 40 minutes, woke up at 7:27am, and spent approximately 29 minutes awake in bed before getting up. Overall sleep efficiency was just above 80%. Results from the analysis at post-intervention indicated that as predicted, participants went to bed 35 minutes earlier then at baseline (β=-0.58, p=.003), there was a significant decrease of 21 minutes in how long participants took to fall asleep (SOL; β=-0.37, p=.032), participants spent significantly less time in bed after waking than they did at baseline (β=-0.27, p<.001), and woke significantly less frequently during the night reducing to an average of 0.87 times (NWAK; β=-0.46, p=.011). There were also improvements in total sleep time of 33 minutes (TST; β=0.53, p=.005), SE (β=5.25, p=.016), how refreshing sleep was (β=0.43, p<.001) and sleep quality (β=0.31, p=.018). There were no significant differences in the time participants woke up in the morning (on average, at 7:20am), TIB, WASO or medication use (all ps>.05). Within-group Cohen's d effect sizes ranged from small to medium (0.31-0.68).

Table 3. Sleep Diary Measures

	Baseline		*Post-intervention*		*Modelled change from baseline- to post-intervention*	
Outcome	*n*	*M (SD)*	*n*	*M (SD)*	*β* [95% CI]	*d*
Time woken up	48	07:27 (0:46)	29	07:20 (0:54)	-0.10 [-0.41-0.21]	-0.13
Time in bed after final morning wake up (h:min)	48	0:29 (0:23)	28	0:13 (0:10)	-0.27 [-0.41, -0.12]***	**-0.70**
Time fallen asleep	48	23:29 (1:19)	28	22:54 (1:03)	-0.58 [-0.95, -0.21]**	-0.44
TIB (h:min)	48	9:39 (1:11)	29	9:38 (0:55)	-0.01 [-0.42, 0.41]	-0.01
SOL (h:min)	48	1:12 (1:01)	28	0:51 (0:47)	-0.37 [-0.70, -0.03]*	**-0.36**
WASO (h:min)	47	0:14 (0:14)	29	0:12 (0:14)	-0.04 [-0.12, 0.05]	-0.17
TST (h:min)	48	7:40 (1:09)	28	8:13 (1:06)	0.53 [0.17, 0.90]**	**0.46**
NWAK	48	1.47 (1.50)	29	0.87 (1.35)	-0.46 [-0.81, -0.11]*	**-0.31**
SE (%)	48	80.12 (12.01)	28	85.64 (11.30)	5.25 [1.03, 9.47]*	**0.44**
Sleep refreshingness	48	2.37 (0.63)	29	2.78 (0.78)	0.43 [0.19, 0.68]***	**0.68**
Sleep quality	48	2.84 (0.74)	29	3.10 (0.82)	0.31 [0.06, 0.56]*	**0.42**
Use of medication	48	0.12 (0.30)	29	0.11 (0.30)	-0.01 [-0.02, 0.01]	-0.03

Note. Raw means (SDs) are presented. Cohen's *d* values are time effects for pre-intervention to post-intervention using the modelled mean difference divided by the sample pre-intervention SD. Time fallen asleep and Time woken up are expressed as times in 24-hour time. Time variables (TIB, SOL, WASO, TST) are expressed in hours:minutes. TIB = Time in bed; SOL = Sleep onset latency; WASO = Wake after sleep onset; TST = Total sleep time; NWAK = Number of awakenings; SE = Sleep efficiency.SE is expressed as a percentage. Refreshingness of sleep is rated on a Likert scale from 1 = *Exhausted* to 5 = *Very refreshed.* Quality of sleep is rated on a Likert scale from 1 = *Very Poor* to 5 = *Very Good*. Use of medication is expressed as a proportion of days medication was used to help with sleep.
* $p < .05$, ** $p < .01$, *** $p < .001$.

Discussion

The purpose of this pilot study was to evaluate the feasibility, acceptability and preliminary effects of the Sleep Ninja app on sleep and mental health symptoms, for use among adolescents with sleep difficulties. A secondary objective of the study was to gather information in order to refine aspects of the app before evaluating it in a larger trial. Our findings confirmed that young people with sleep difficulties were optimistic about using the app and could complete baseline questionnaires and sleep diaries using an automated digital format without assistance. Feasibility was confirmed based on uptake, completion and retention rates with young people volunteering for the study, downloading the app and completing most of the lessons. This provides evidence that the Sleep Ninja app is a feasible intervention to deliver to young people experiencing sleep difficulties.

Intervention adherence levels suggested that while more than half of the participants completed more than half of the app, only one third of participants completed all six lessons. While this is within the range of adherence rates reported in the literature for technology-mediated insomnia programs [44], reasons for non-adherence require consideration as there is room for improvement. The main reason participants had difficulty or stopped using the app was reportedly due to the amount of text presented in the app and the repetitive nature of the material. Participants also requested a more tailored experience. Those who completed more of the app also reported it to be more acceptable. Therefore, it is likely that refining the app by taking these points into account is likely to increase engagement with the content and overall adherence to the intervention.

Efficacy outcomes showed that insomnia symptoms improved significantly from baseline to post-study, effectively moving participants from the lower cut off for clinical insomnia, firmly into the sub-threshold symptom level. There was an improvement in self-reported sleep quality, with a medium effect size (d=-0.46) suggesting app use improves

quality of sleep. The improvements detected on the two sleep questionnaire measures (ISI, PQSI) were corroborated by those found in the sleep diaries, with participants going to bed earlier, falling asleep more quickly at night, waking less frequency, sleeping for longer, spending less time in bed in the morning after waking, and reporting improved sleep efficiency and quality.

The time that participants reported waking each morning did not shift. This finding needs to be considered in the context of young people having to get up at a specific time for school each morning. School start times are a modifiable contributing factor to insufficient sleep, with evidence suggesting that delaying school start times by even 30 minutes is associated with higher levels of school attendance, lower daytime sleepiness, and improved attention and concentration [45]. While there have been calls to delay school start times to improve sleep duration, health and functioning (e.g., [46]), this is unlikely to change in the Australian context. Accordingly, a focus on bed times rather than rise times is likely to be most useful for treating sleep difficulties in this age group, at least for the time being.

Findings on these sleep outcomes are consistent with the two studies which have evaluated web-delivered CBT-I for adolescents with insomnia [15, 16, 17), and show for the first time that CBT-I, when delivered to adolescents by smartphone-app, confer benefits. It is encouraging that the within-group effect size obtained in the current study for insomnia (d=-0.90) is comparable to within-group effect size found for digitally-delivered CBT-I in a randomised trial (d=-0.92; [16]). In this randomised study, the intervention group was found to be superior to the waitlist control, suggesting that a within-group effect size of this magnitude is likely to reflect improvement over and above what would be expected based on a standard placebo effect [16].

Beyond the sleep outcomes, we also found that there were decreases in depression and anxiety symptoms following the completion of the intervention suggesting that there may be

value in using this app to address mental illness. The magnitude of the decrease in depression scores is notable, with individuals moving from the moderate range into the mild range, and a within-group effect size that is comparable to other adolescent depression prevention trials [47]. These findings provide proof-of-principle evidence that the Sleep Ninja app may be useful in addressing depression. As a pilot study, we did not test the specific hypothesis that targeting insomnia will decrease depression risk. Given our encouraging findings, a follow-up randomised controlled trial which follows participants over time, which can determine causality between insomnia and depression, that can assess the mechanisms of change, as well as the impact of intervention on depression risk is now warranted.

This study makes a unique contribution to the literature by showing that smartphone delivery of CBT-I is a promising format in which to deliver this gold-standard intervention. This is the first study that we are aware of that has evaluated app-delivered CBT-I in young people [21], and only the second study that has tested mobile phone delivery of CBT-I, the first study being conducted in adults, with positive effects on sleep outcomes [48]. Using smartphones to deliver interventions such as this offer a myriad of advantages, including immediate connectivity to automated interactive applications that can be accessed anytime, anywhere. Sleep Ninja has been developed so that it does not rely on internet access for use, which is likely to be important to young people who may have limited data plans, and individuals who do not have optimal internet coverage. Not requiring internet coverage to access digital programs represents a new wave of flexibility in the delivery of health interventions and the automated nature of the intervention means it can be delivered without professional support. It is notable that we had a 72% retention rate, which is at the upper level of that detected for digital interventions which has been shown in a meta-analysis to range between 43-99% [49], with retention rates typically lower in non-supported interventions [50].

There are several study limitations that need to be considered. First, participants in this trial were required to have relatively minor levels of insomnia symptoms for study entry. This decision was made by balancing inclusiveness against the requirement of sleep disturbance to ensure participants were motivated to use the app. Moreover, given the study focus was on feasibility and acceptability, we felt it would be prudent to establish these factors before targeting a more severe participant group. That said, while we set the threshold for entry relatively low, both the mean and the median converged on an ISI score of just above 14, indicating that participants were at the junction between having subthreshold and clinical levels of insomnia symptoms (cut-off score is 15). Therefore, it is relatively unlikely that there would have been a floor effect as the data showed there was sufficient room to detect symptom-improvement. The high mean symptom level also suggests that the results may generalise to a group with clinical levels of insomnia. Second, we did not include a control group. Again, as the study goal was to establish feasibility and acceptability, it was not necessary to include a control group for this purpose. However, this design is not able to attribute causality to the intervention and a controlled study is now needed. Finally, this study relied exclusively on subjectively reported sleep outcomes. Although objective measures such as polysomnography provide the most accurate way to assess sleep, there is evidence that subjectively measured sleep variables could be more closely associated with functional outcomes [51]. Moreover, subjectively experienced sleep quality and parameters have consistently shown to be strongly associated with psychological wellbeing [52, 53], suggesting that perception of sleep is as important, if not more so, than objective measures. We are currently investigating how inbuilt smartphone sensors such as the accelerometer might be used to provide a more objective estimate of sleep.

This study provides preliminary evidence supporting the feasibility, acceptability and effects of a fully-automated app that targets adolescent sleep difficulties. The Sleep Ninja

intervention shows promise both as a sleep-focused intervention, but also potentially to reduce risk for depression.

Figure Legends

Figure 1. Example screens from the Sleep Ninja app. From left: Homescreen, Training Session Access and Progress Record, Tracking and Bedtime Setting, More Information

Figure 2. Participant Flow

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Author Statement

AW-S, BO, MT and HC conceived of the study and the trial design. AW-S designed the study with input from all authors, and oversaw the management of the trial. LJ led trial recruitment, managed the day-to-day running of the trial and conducted the participant interviews. QW conducted the analyses with assistance from AW-S and LJ. All authors contributed to the preparation of the manuscript.

Competing Interests Statement

No competing interests to declare.

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Data Sharing Statement

No additional unpublished data from this study is publicly available.

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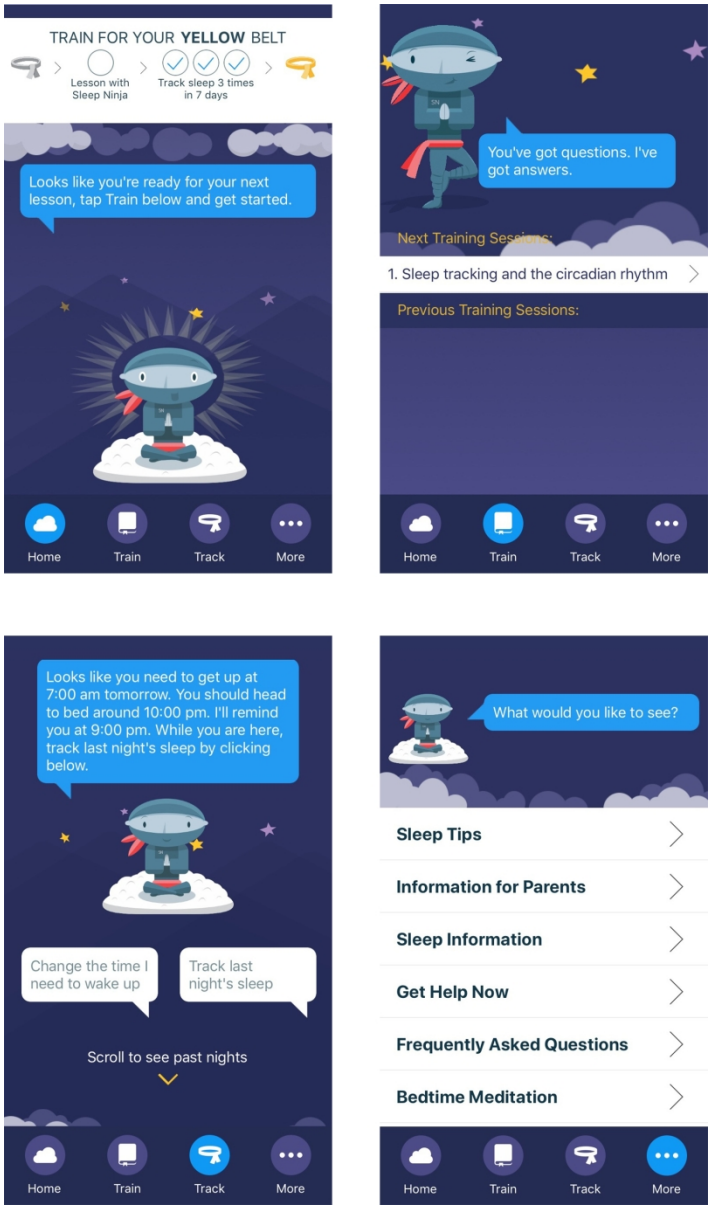

Figure 1. Example screens from the Sleep Ninja app. From left: Homescreen, Training Session Access and Progress Record, Tracking and Bedtime Setting, More Information

139x238mm (300 x 300 DPI)

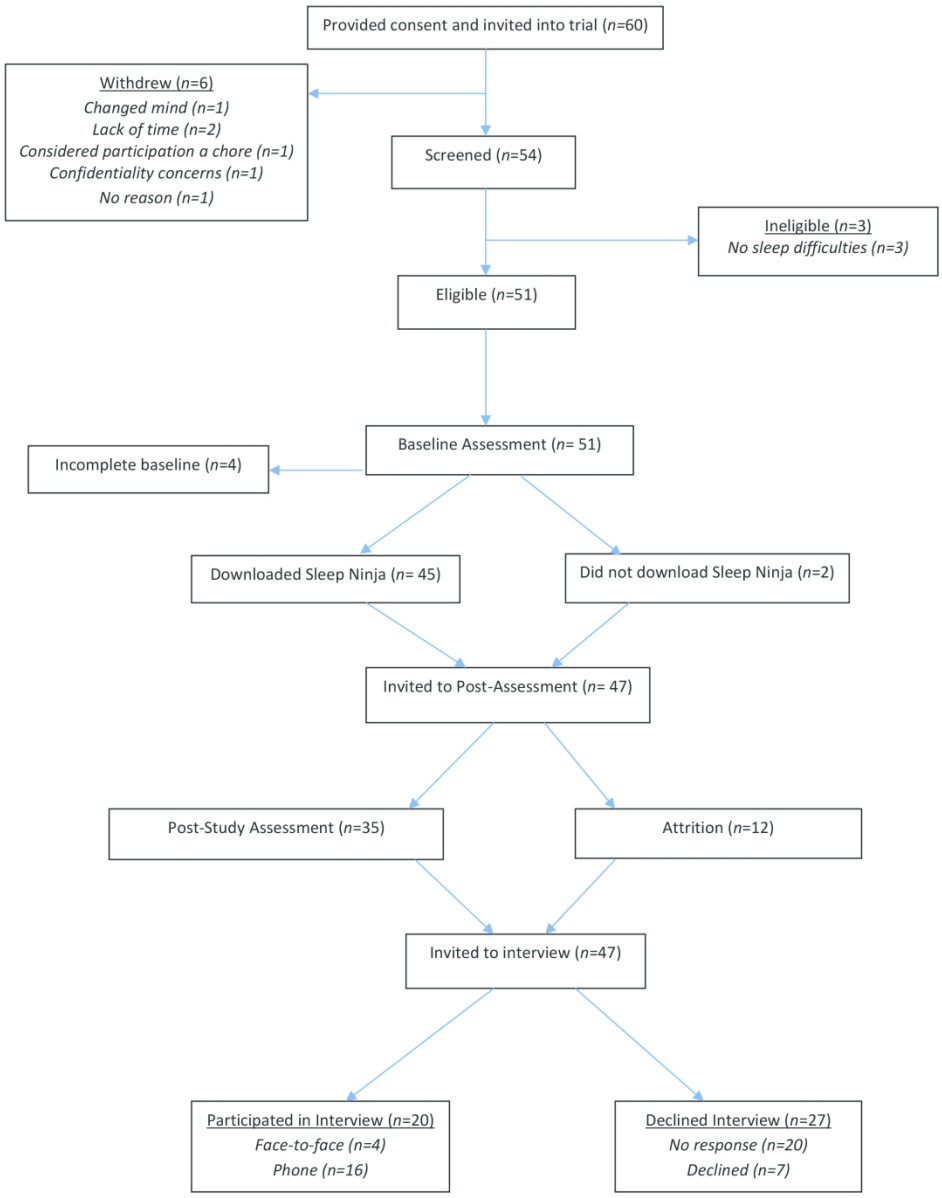

Figure 2. Participant Flow

187x238mm (300 x 300 DPI)

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	5-6
	2b	Specific objectives or research questions for pilot trial	6
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	6
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	7
	4b	Settings and locations where the data were collected	13
	4c	How participants were identified and consented	13
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	11-12
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	7-11, 13
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	N/A
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	N/A
Sample size	7a	Rationale for numbers in the pilot trial	7
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	N/A
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	N/A
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	N/A

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	N/A
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	N/A
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	14-15
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	Figure 2
	13b	For each group, losses and exclusions after randomisation, together with reasons	16
Recruitment	14a	Dates defining the periods of recruitment and follow-up	7
	14b	Why the pilot trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1, p. 15
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	Table 2, p. 19 Table 3, p. 21
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	Table 2, p. 19 Table 3, p. 21
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	16-19
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
	19a	If relevant, other important unintended consequences	N/A
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	25
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	23-24
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	22-23
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	24
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	7
Protocol	24	Where the pilot trial protocol can be accessed, if available	N/A
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	28
	26	Ethical approval or approval by research review committee, confirmed with reference number	13

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.
*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.