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Title: A feasibility study of a mobile app to treat insomnia

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Abstract

Background: Insomnia is a major public health concern. Sleep restriction therapy (SRT) is an effective behavioural treatment but its delivery is impeded by a shortage of trained clinicians.

Purpose: We developed a mobile app delivering SRT to individuals with insomnia. This feasibility study employed a mixed-methods design to examine the engagement, acceptability and potential efficacy of the mobile app.

Methods: Fifteen participants diagnosed with Insomnia Disorder used the mobile app synchronised with a wearable device for 3 weeks.

Results: Those who persisted with the study (n=12) found the mobile app to be highly acceptable and engaging, logging on average 19 nightly sleep diary entries across the 21-day period. Significant improvements were observed for sleep measures (insomnia severity and sleep efficiency) and daytime symptoms (fatigue and sleepiness).

Conclusions: The results suggest a mobile app delivering SRT to individuals with insomnia is engaging, acceptable and potentially efficacious. Further, a full-scale effectiveness study is warranted.

Keywords: mHealth, mobile apps, sleep, insomnia, cognitive behavioural therapy, eHealth

Introduction

Insomnia is a prevalent health problem affecting up to 12% of the adult population, however it remains under recognised and undertreated [1; 2]. Cognitive behavioural therapy for insomnia (CBTi) is an effective first-line multicomponent treatment which has consistently shown moderate to large treatment effects [3-5]. Despite this, a major barrier to the widespread use of CBTi has been a shortage of skilled practitioners to treat the high volume of insomnia patients [6].

Research has increasingly explored digital technologies delivering behavioural interventions to facilitate treatment access to a larger number of people. A recent meta-analysis showed that digital CBTi (dCBTi) has comparable effect sizes to face-to face therapy [7]. A single-treatment component of dCBTi has

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similar utility in treating insomnia but as such has not been investigated. In addition, the majority of existing research is limited to web-based interventions rather than mobile.

In comparison to internet interventions, mobile phones can extend reach and utilisation given their ubiquity, convenience and portability. There is emerging evidence for mobile health (mHealth) apps in supporting health issues including depression, anxiety, schizophrenia, cardiac disease, physical activity and diabetes [8-12]. However, evidence-based mobile apps targeting sleep remain in their infancy [13]. To our knowledge, there are five studies examining dCBTi delivered via mobile [14-18]. All of these mobile apps deliver multicomponent cognitive behavioural therapy with only one study exploring a standalone app to treat insomnia [14].

To address this current gap, we developed a fully automated mobile app delivering sleep restriction therapy (SRT), a single, highly effective component of CBTi [19]. The aim of this study was to evaluate the feasibility of this mobile app in individuals with insomnia. Guided by Bowen et al. [20], we used three major dimensions of feasibility: (1) engagement, measured by objective usage of the mobile app, (2) acceptability, measured by self-report questionnaires and qualitative data and (3) preliminary efficacy, evaluated by changes in sleep and mental health measures, and qualitative data. The overall aim of this feasibility study was to determine whether the mobile app would be appropriate for subsequent testing in a larger scale effectiveness evaluation [21; 22].

Methods

Participants

Participants were recruited from March to May 2018 via online advertisements and clinician referrals.

Inclusion criteria were (1) ≥ 18 years, (2) owners of a mobile phone, (3) literate in English, (4) Insomnia severity index (ISI) score ≥ 15 [23; 24], (5) Pittsburgh sleep quality index (PSQI) global score > 5 [25], and (6) diagnosed with insomnia disorder by a sleep clinician as defined by the Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5) [26]. Participants were excluded for the following reasons: (1) pregnancy or lactating, (2) shift work, (3) substance dependence, (4) severe psychiatric illness, (5) other sleep disorders other than insomnia, (6) severe cognitive impairment which may affect consent and participation, and (7) recent time-zone travel within the last month. The study was approved by the

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Sydney Local Health District Ethics Committee (X17-0425) and registered at Australian New Zealand Clinical Trials Registry (ANZCTR; Registration number: ACTRN12618000060246).

Procedure

Potential participants completed the ISI and PSQI online and telephone screening for inclusion and exclusion criteria. These participants were invited to the Woolcock Institute of Medical Research (WIMR) for clinical diagnosis by the study sleep physician. Eligible participants diagnosed with insomnia were invited to complete informed consent. Consenting participants attended a face-to-face information session about sleep restriction therapy and were taught how to set-up and use the proof-of-concept mobile app. Participants also received a Fitbit for sleep tracking and synchronisation with the app. All participants were instructed to use the mobile app and wear the Fitbit for 3 weeks. During weeks 1-3, participants were called twice weekly by the study coordinator to discuss any barriers and help with questions about therapy. Participants returned to the WIMR at week 6 and underwent another clinical evaluation and a qualitative interview.

Intervention

The fully automated mobile app delivered a behavioural component of CBTi, namely SRT. This treatment is a powerful standalone behavioural intervention is a modifier of sleep disturbance associated with insomnia [19]. SRT aims to consolidate fragmented sleep by closely matching average reported sleep duration with total time spent in bed. The sleep window is typically titrated up or down by 15-minute increments/decrements depending on sleep efficiency (the proportion of time spent asleep while in bed). The therapy induces mild sleep deprivation in order to build homeostatic sleep pressure [27]. To commence the 3-week therapy, users completed initial questions asking for their average sleep time and time spent in bed (including time spent awake). The app then calculated the initial prescribed sleep window using an algorithm with a minimum sleep window of 5.5 hours. Each morning, the app automatically presented the user with the sleep diary. The app was also synced with a Fitbit to gather objective sleep data. Users were presented with this data prefilled in the diary and were able to modify this if they felt it was inaccurate. The app reviewed sleep diary data every three days and adjusted user's sleep window to either extend or restrict their sleep window by 15 minutes. Progress could be reviewed from

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graphical displays of sleep efficiency and sleep satisfaction.

Optional functions of the app included a mood widget adapted from *Headgear*, an existing mental health mobile app [28] which allowed users to record their mood. The games section included an interactive game to test users' concentration.

Measures

Engagement and acceptability

Engagement was measured by participant usage of the sleep diary, mood logger and game was recorded automatically. Acceptability was assessed using the System Usability Scale (SUS) and semi-structured interviews at week 6. The SUS is a 10-item measure assessing usability and user satisfaction with technology [29]. We added two additional items asking whether the user would recommend the app (5-point Likert scale from 0 "not at all" to 4 "very"), and an overall assessment of user friendliness on a 7-point Likert scale from "worst imaginable" to "best imaginable". The SUS has shown high internal consistency ($\alpha = 0.91$) [29]. Semi-structured interviews were conducted by the study psychologist (DB) or first author (MA) using a topic guide. The interviews explored participants (1) experience with the study, (2) experience with the app and (3) general phone usage and previous health app experience. Interviews lasted 10-30 minutes and were audio-recorded and transcribed.

Preliminary efficacy

Insomnia severity over the previous two weeks was measured by the ISI [23; 30], a 7-item quantitative index. Scores range from 0 to 28 with moderate-severe insomnia defined as >15 . The PSQI [25] is a 19-item tool assessing subjective sleep quality over the previous month. It comprises seven components summed to yield a "global" score (range 0-21). In-app sleep diary and Fitbit data included the time users went to bed and woke up, SOL and WASO. Data from the sleep diary entries were used to calculate the time in bed (time went to bed – wake time), total sleep time (time in bed-SOL-WASO) and sleep efficiency (total sleep time/time in bed x 100). Daytime sleepiness and fatigue was measured by the 9-item Epworth Sleepiness Scale (ESS) [31] and 7-item Flinders Fatigue scale (FFS) [32], respectively. Anxiety and depression was measured by the 14-item Hospital Anxiety and Depression scale [33]. Health-related quality of life was measured by the Short Form Health Survey (SF-12) [34] with scores transformed into a mental composite summary (MCS) and physical composite summary (PCS) score. For all measures,

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higher scores indicate worse functioning except for SF-12. Preliminary efficacy was also assessed by a qualitative analysis of semi-structured interviews.

Data analysis

Statistical analyses were carried out on completers (n=12) using R. Statistical significance was defined at the 95% confidence level ($p < 0.05$, 2-tailed). Descriptive statistics were computed. Changes in outcomes were measured using t-tests, repeated measures ANOVA and Wilcoxon Signed Rank tests.

Interview data were analysed by the first author (MA) using inductive thematic analysis. The coder examined the transcripts and generated initial codes. After emerging themes were determined, analysis progressed iteratively and codes were refined into themes and subthemes. To ensure validity, a second researcher (DB) independently read and coded the transcripts and examined the first author's coding scheme. After discussion, the revised themes detailed in the results were agreed on by both authors.

Results

Of the 93 who registered, 58 were telephone screened and 19 were invited for assessment by a sleep physician (Figure 1). Fifteen participants consented and of these, 13 used the program for 3 weeks and 12 completed follow-up assessments. All participants were female. The mean age was 40.0 years and the average duration of insomnia disorder was 5.6 years (See table 1 for completers baseline characteristics).

Insert Figure 1. Table 1. Baseline characteristics of sample

Characteristic	Value (n=12)
Age, mean (SD)	40.0 (14.2)
Sex, n (%)	
Female	15 (100)
Duration of insomnia in years, mean, (SD)	5.6 (5.0)
ISI, Mean (SD)	19.0 (3.3)
PSQI, Mean (SD)	13.3 (2.4)
PSQI SE, Mean % (SD)	68.3 (15.7)
FFS, Mean (SD)	18.8 (5.2)
ESS, Mean (SD)	9.7 (4.8)
SF-12 Physical health (PCS), Mean (SD)	42.9 (11.6)
HADS-Anxiety, Mean (SD)	9.8 (4.3)
HADS-Depression, Mean (SD)	7.3 (4.9)

ISI: Insomnia Severity Index

PSQI: Pittsburgh Sleep Quality Index

FFS: Flinders Fatigue Scale

ESS: Epworth Sleepiness Scale

SF-12: Short-form 12 Health Survey

HADS: Hospital Anxiety and Depression Scale

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Engagement and acceptability

The 13 participants who used the app for the full 3 weeks averaged 19 (SD 3.6) nightly sleep diaries with only 2 individuals entering fewer. On average, participants logged 12 (SD 10.1) mood entries. There was considerable variability in game usage (average 37 game sessions, SD=97.7, range 0-361). The mean SUS was 69 points (SD 14), above the score of 68 points considered as “acceptable” [29]. Participants rated the user-friendliness of the app ‘okay’ (4.9/7). Ninety-two percent would recommend the app to their friends and family.

Of the 13 participants who engaged in the app, we conducted semi-structured interviews with 12 completers. Figure 2 presents the themes and subthemes of acceptability derived from the interviews.

Insert Figure 2. Initial perceptions and experience of the therapy

Challenging adjustment

Participants explained preliminary thoughts of the therapy as “intimidating” (P1), “a struggle” (P12), “really hard” (P3, P11) and “pretty torturous” (P4). In particular, participants emphasised difficulty staying awake until their prescribed bedtime given their commonly experienced side-effects including fatigue and sleepiness. One participant explains this challenging but temporary initial period:

“The tricky part is people don’t like to suffer, they don’t like to be uncomfortable, but it’s going to get better.” (P14)

Several participants expressed difficulties incorporating the rigid sleep schedule into fluctuating daily life:

“For someone who works a job where start times may be adjusted - hard to be able to do that within life.” (P10)

Simplicity and logic of the therapy

Amongst the taxing and difficult symptoms experienced, participants found comfort in the therapy’s simple and logical directives described as “pretty straightforward”, “not rocket science” (P4) and “very easy to follow” (P14):

“The concept is really simple – don’t stay in bed when you can’t fall asleep.” (P13)

Many participants appreciated learning about the concept behind sleep restriction therapy from the initial start-up screen. Several participants found sleep efficiency a useful and holistic measure:

“I like seeing the sleep efficiency. I’ve never thought to compute it that way. Because you have apps telling you how much awake you are at night and seeing the value of sleep that’s more than just the duration you’re actually sleeping.” (P9)

App features and functions

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Preference for further complexity

Although most participants appreciated the simplicity of the therapy and minimal time-commitment (“*It was nice to be able to have a small 2 second app.*” - P3), paradoxically some expressed interest in “*more complicated*” features and functions (P4). Given the relative ease of administration of the therapy, participants suggested more complex features and functions such as access to professional advice, real-time feedback, sleep stage tracking and increased gamification to reward adherence. Although participants enjoyed the champion feature of the app which sends emails detailing the participant’s progress to their selected supporter: (*I liked the app asked you to nominate the buddy.*” - P7), there was a further need for complex social support features to discuss experienced symptoms.

The importance of synchronisation

Several participants endorsed the streamlining of processes to ensure minimal burden on the user. For example, the ability to synchronise Fitbit data was appreciated by nearly half of participants:

“I liked that it was integrated ...it syncs across and it just works from there so you’re not thinking about all the things you need to do. It’s slowly helping you in the right direction.” (P6)

Additionally, users expected the app (in conjunction with Fitbit) to provide objective measures of sleep metrics in order to increase usability. In particular, participants expressed frustration in the app’s inability to measure SOL thereby requiring manual data entry:

“If the core function of it [the app] is to make sleep consolidation therapy more user friendly, to require people to have to do that calculation, I don’t think necessarily it’s time saved.” (P10)

Not only did this impact user experience but was also noted as a psychological burden for one user:

“You’re putting more pressure on people when you ask how long it takes you to fall asleep – you’re not helping the person go to sleep. You need to have some indication.” (P4)

Identifying patterns and trends in sleep

Some participants found it helpful to review their in-app sleep diary and graphs and Fitbit graphs.

Although the “sleep tags” feature allowed users to note a pre-defined tag (e.g. alcohol or meditation) against their sleep diary, several individuals suggested the addition of personalised tags in a free field box.

“This would be more effective in tracking your own personal reasons as to why your sleep might be affected.” (P10)

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Moreover, a user suggested the addition of visual tags alongside the existing graphs of sleep efficiency and satisfaction. Enhancing the interpretability of these graphs would assist data interpretation.

Subjective quality

Participants rated the apps ease of use 8.6 out of 10 with 1 = very hard and 10 = very easy. The app attracted an overall average star rating of 4.5 and 83% would pay for the app.

Treatment outcomes

Repeated measures ANOVA revealed significant improvements between baseline and week 6 in ISI ($F_{2,22} = 27.3$; $P < 0.001$), FFS ($F_{2,22} = 9.6$; $P < 0.001$), and ESS ($F_{2,22} = 4.05$; $P < 0.001$) (Figure 3a-c). Paired t tests showed significant improvements in sleep quality between baseline and week 6; PSQI total score ($t(11) = 7.18$; $P < 0.001$), and PSQI SE ($t(11) = -3.7$; $P < 0.001$). There was a trend towards an improvement in SF-12 physical health (PCS) and a reduction in HADS anxiety and depression however these were not significant (physical health, $t(11) = -2.03$, $P = 0.06$, anxiety, $Z = -1.56$, $P = .12$, depression, $Z = -1.8$, $P = 0.07$).

Insert Figure 3a - c. There were no significant changes in sleep diary or Fitbit outcomes during the treatment period (Table 2).

Table 2. Sleep diary outcomes

Variable	Week 1	Week 2	Week 3	Statistics
Diary SE, %	85 ± 6.8	85 ± 7.7	83 ± 6.0	F=0.12, P = 0.89
Diary WASO, mins	53 ± 34.1	54 ± 40.5	60 ± 33.1	F=0.56, P = 0.58
Diary SOL, mins	30 ± 39.3	15 ± 12.8	30 ± 46.1	F=0.63, P=0.54
Fitbit SE, %	87 ± 4.7	87 ± 4.3	85 ± 8.0	F=1.58, P = 0.23
Fitbit WASO, mins	49 ± 12.8	45 ± 8.8	53 ± 18.1	F=1.96, P=0.17

SE: Sleep efficiency

WASO: Wake after sleep onset

SOL: Sleep onset latency

Qualitative analysis of treatment outcomes

Perceived sleep-related improvements

Changing maladaptive sleep beliefs

A shift in dysfunctional beliefs related to sleep duration was experienced by several participants (3/12).

Prior to the study, participants had a fixed idea of the hours of sleep required. By the end of the study many realised that despite the shorter duration, increased sleep quality was observed:

“I did feel like I was getting more out of the sleep that I was getting, even if it was shorter. When I wake up, I’m actually rested.” (P9)

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Reduced insomnia symptoms and anxiety

All participants reported sleep-related improvements following treatment such as reduced SOL, increased consolidation and quality. The most common improvement was reduced anxiety around sleep (5/12).

“I do start to wake up in the middle of the night quite often, but like, before I used to feel stressed about waking up and not able to fall asleep. Now when I wake up, I go straight back to sleep. Great improvement.” (P13)

Discussion

This study showed that a standalone mobile app delivering SRT is feasible in individuals with insomnia.

This was evidenced with high levels of engagement, acceptability and potential efficacy. The majority of participants used the app daily to record their sleep 90% of the treatment period. Users were less likely to use the supplementary app features including the mood widget and game despite these features available to be used daily.

Overall, the app was well received and found to be acceptable by users. Qualitative data found the app was easy to follow and usable with participants adding that the app’s streamlined processes such as synchronisation of wearable device data enhanced its user-friendliness. These findings of good acceptability mirror other mHealth feasibility studies wherein users of mobile apps for insomnia report this is an acceptable mode of delivery and would be used again [15; 18]. Similarly, a recent systematic review assessing apps for anxiety revealed moderate to high ratings for usability, helpfulness and satisfaction [11].

These results suggest a simple and easy treatment experience. However the interviews highlighted both initial apprehension and challenging side-effects. In particular, participants stressed the discomfort and difficulty in adhering to a rigid and shortened sleep window. Given these initially taxing symptoms, the app’s ease of use and straightforward therapy directives may have aided this period of early adjustment. To alleviate the therapy’s challenging nature, participants suggested the addition of further social support which could aid adherence and allow them to connect with others with similar symptoms. Participants noted additional areas for improvement such as the inclusion of engaging and complex app features (e.g. real-time feedback and sleep stage tracking); features to aid data interpretation; and further minimising user burden.

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Preliminary assessments of the mobile interventions efficacy suggested that use of the app produces improvements in insomnia and sleep symptoms. Statistically significant and clinically meaningful reductions were observed in insomnia severity with an average drop of 11 points on the ISI (clinical improvement defined as a change of >8 [24]). The mobile app also had a significant positive effect on sleep quality, sleep efficiency (PSQI), fatigue and daytime sleepiness. Qualitative data echoed these findings with participants reporting a reduction in sleep-related anxiety and maladaptive sleep beliefs. Despite this, there was no significant reduction in the HADS anxiety subscale, potentially attributable to a small sample size. Nevertheless, this highlights the importance of a multimethod exploration where granularity obtained from a qualitative analysis allows for a more robust understanding of findings. The clinical outcomes in the current study are comparable to other feasibility studies of digital interventions delivering CBTi. Espie and colleagues [35] and Ritterband and colleagues [36] both administered a fully automated web-delivered CBTi program, delivered as a 6- 9 week intervention. Both programs involved multi-component CBTi (including SRT) and showed statistically significant improvements in insomnia severity and sleep efficiency. These findings are supported by a meta-analysis of dCBTi interventions reporting sustained improvements in insomnia severity, sleep efficiency and sleep quality [7].

Such outcomes are also comparable in magnitude to mobile-delivered CBTi. A randomised clinical trial delivering a fully automated mobile app showed moderate significant effects ($d=-0.66$) on insomnia severity compared to a wait-list control [14]. Whereas, a mobile app delivering CBTi adjunct to group therapy and synchronisable with a Fitbit found a similar reduction in ISI [15]. Our results showed comparable improvements with a single component of dCBTi.

This study has several limitations. First, the sample size was relatively small and therefore the statistical power is weak. Second, the study had no control arm and therefore the results explained by regression to the mean cannot be excluded. Third, all participants were female which may limit generalisability. Finally, there was a potential influence of the study coordinator/participant relationship. The primary researcher (MA) carried out the initial face-to-face session, telephone check-ins and follow-up interviews. Given this close involvement, potential bias and reactivity may have been introduced in the interviews. Although

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participants valued the human communication, the digital mode of delivery was indicated as largely acceptable. Strengths include the low attrition rate and mixed methods approach in capturing both quantitative and qualitative data to provide an in-depth examination into user experience.

The current study demonstrated improvements comparable to both web- and mobile-based interventions, notably, delivering only one component of CBTi (SRT) over a shorter treatment duration time (3 weeks). Earlier research found an association between longer treatment duration of web-delivered CBTi and larger effect sizes [7]. Therefore, investigating whether SRT, one of the most efficacious standalone components of CBTi, produces comparable results delivered over a shorter time period is important. In addition, future work would benefit from exploring whether mode of delivery (i.e. web vs. mobile) has an impact on feasibility. Our approach to assessing our mHealth app follows the framework from the National Institute for Health and Care that sets the quality and evidence base standards for digital interventions [22]. Best practice of 'Acceptability standards' for Tier 1 Level evidence requires published evidence of user involvement in intervention design, development, testing and user satisfaction data. The current study in conjunction with a previous paper exploring user preferences and needs were undertaken to satisfy these requirements [37]. Taken together, this feasibility study demonstrates the potential of our mHealth app in treating individuals with insomnia and supports further testing in a full-scale trial.

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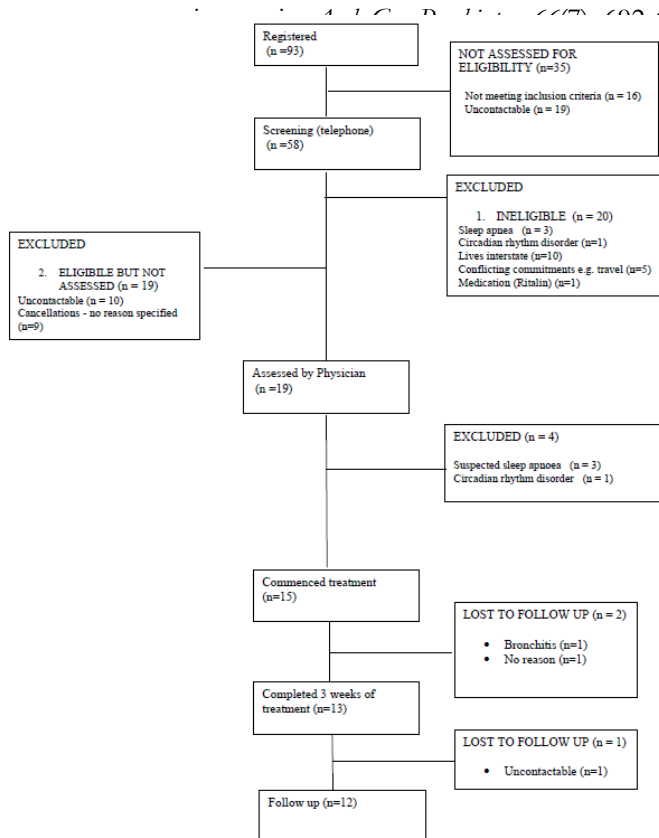


Figure 1: Participant flow through the study

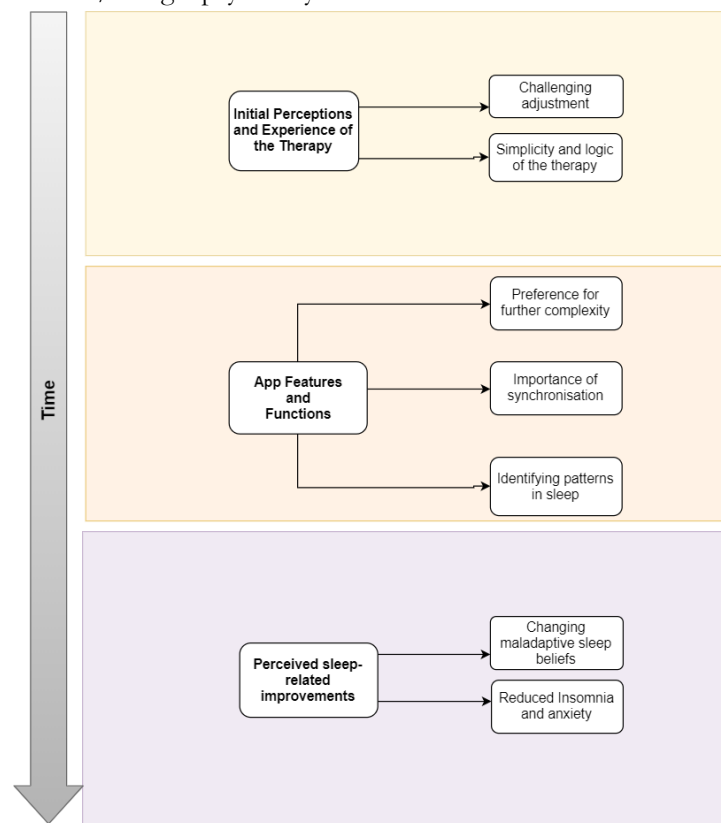


Figure 2. Thematic schema of perceptions and experience of the mobile app

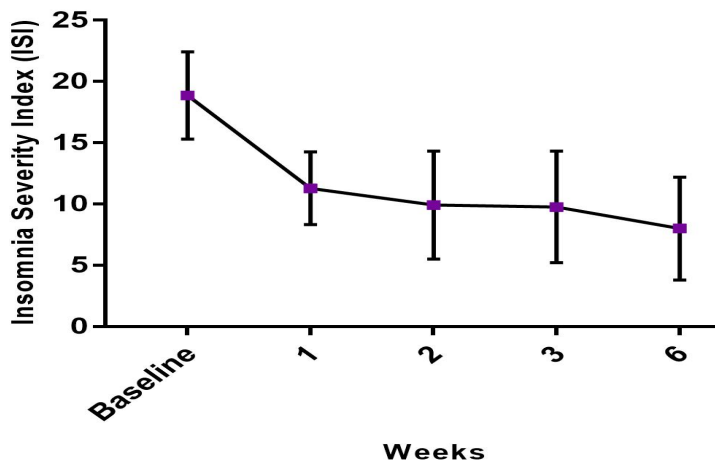


Figure 3a. Change in ISI scores. Data are means with standard deviations.

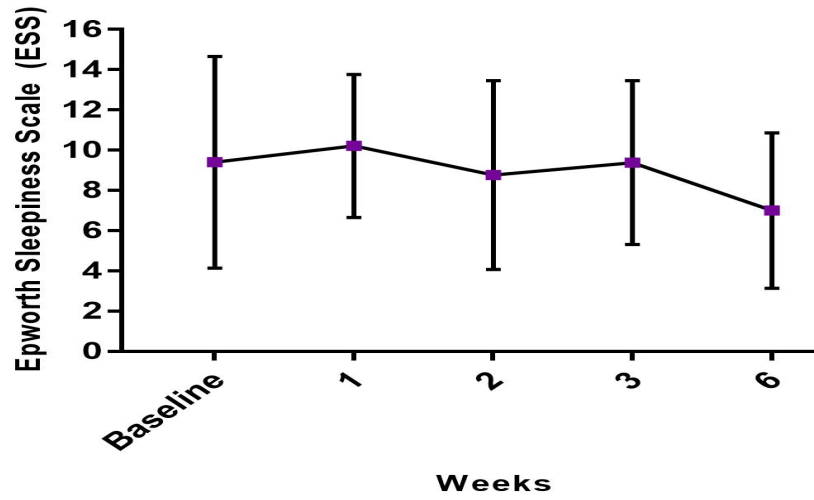


Figure 3b. Change in ESS scores. Data are means with standard deviations.

Figure 3c. Change in FFS scores. Data are means with standard deviations.

