

SLEEP BETTER

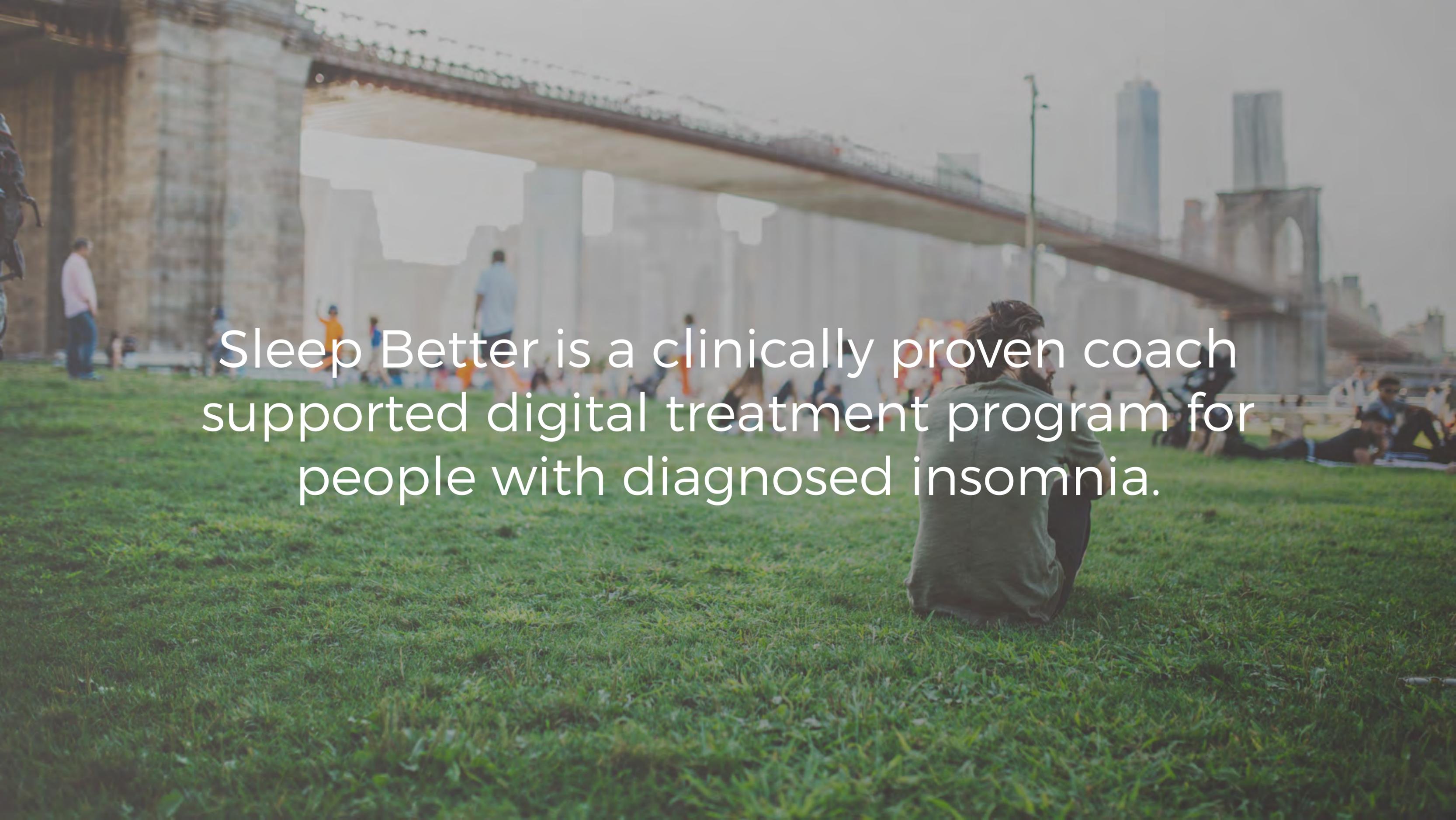
(Sov Bättre)

Pilot Study (2014) and
Clinical Evaluation
(2015)



LEARNING
TO SLEEP



A man with a beard, wearing a green t-shirt, is sitting on a lush green lawn, looking towards a city skyline. In the background, a large stone bridge with multiple arches spans across the scene. The sky is overcast, and several other people are visible in the distance, some sitting on the grass. The overall atmosphere is calm and contemplative.

Sleep Better is a clinically proven coach supported digital treatment program for people with diagnosed insomnia.

SUMMARY

Learning to Sleep helps people with diagnosed moderate to severe Insomnia getting better sleep through clinically proven products distributed through mobile and web solutions. We have a history of **more than 4 years of research studies** and have become one of the leading mobile health companies in Sweden.

This report shows the results from two evaluations done when Sov Bättre was introduced on the Swedish market:

- Pilot study done in fall 2014 with 18 patients in total
- Full scale evaluation done in fall 2015 with 56 patients in total

Both evaluations was done in collaboration with Pfizer Sweden and Previa (the main provider of occupational health in Sweden). The groups of patients were evaluated by a doctor and diagnosed with Insomnia according to ISI (Insomnia Severity Index). Patients were excluded according to the exclusion criteria provided by Learning to Sleep (see appendix 1). In the pilot study a follow up was done directly after the treatment and a second follow up was done 12 weeks after completed treatment. In the full scale evaluation the second and third follow up was done 6 and 12 months after completed treatment.

The pilot study and the full scale evaluation shows equal results:

- The **average improvement was 10.4** points on the ISI scale in the full scale study
- In the pilot study 83 percent of the patients had an improvement of 3 or more on the ISI scale
- In the full scale study **94 percent** of the patients had an improvement of 3 or more on the ISI scale (this can be compared with 65-70 percent in traditional treatment by a psychologist).
- 9 out of 10 also said they would recommend Sov Bättre to somebody else.

Normally the drop out rate is high (> 80 percent) in digital products. The combination of a digital product and a sleep coach **reduced the drop out rate to under 8 percent**, which is a very good result. In comparison to other products on the market, and also traditional treatment, Sov Bättre has the lowest drop out rate so far.



PROBLEM, SOLUTION AND BACKGROUND

Approximately 20 percent of the world's population suffers from severe sleeping disorder and Insomnia, causing huge problems both for the individual and society. Bad sleep is closely connected to other health issues such as obesity, diabetes and cardiovascular diseases. Traditional drug treatment is proven to be much less effective than Cognitive Behavioural Therapy (CBT) when treating sleeping problems, and the lack of nearly 100 000 therapists in US creates a huge availability problem.

Learning to Sleep started as early as 2012 to do research on how to help people with sleeping problems to get better sleep through CBT-based digital platforms. The first tests with mobile applications had over 40 000 downloads and we know today that **9 out of 10** gets improved sleep with CBT through our digital products.

When Peter Boye (CBT therapist specialising on sleep) and Helena Kubicek (psychologist and Sweden's leading sleep expert) started Learning to Sleep they were the pioneers in Sweden within e-health solutions. This was even before the expression mobile health was being used. Their vision were to create products that were accessible at any time and any place, but also affordable for everyone to buy.

The solution was Sleep Better (Sov Bättre), a coach led digital CBT treatment for persons with diagnosed Insomnia. The program was developed in 2013 as a joint project together with Pfizer Services in Sweden and is today fully owned by Learning to Sleep.

During the past years Learning to Sleep have spent time studying how a digital and mobile platform should be designed in order to give the best result and highest compliance possible, when treating sleeping problems. Today Learning to Sleep is the **leading brand** for digitalised DIY sleep treatment in Sweden and everything is based on research and is, of course, approved by relevant authorities.

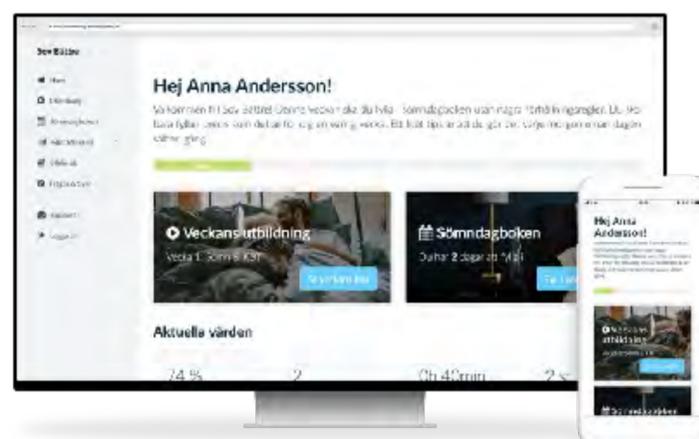
Learning to Sleep was selected in 2016 to be part of the Plug and Play Health Tech Accelerator sponsored by Johnson & Johnson. 11 companies were chosen to participate in the program from a total of approximately 1000 applicants and Learning to Sleep was the only company from outside the US.



THE SLEEP BETTER PROGRAM

Sleep Better is a 5 week coach supported digital treatment program targeting persons with diagnosed moderate or severe Insomnia. The program is based on Cognitive Behavioural Therapy in combination with sleep restriction in order to reset the body's sleep cycle.

The program starts when the patient logs in to the system for the first time and makes an appointment (on remote) with the individual sleep coach. Every week has a new theme with psychoeducative videos and tasks. This gives the patient a number of different tools in order to change behaviour connected to sleep.



The sleep coach is connected with the patient through a back end system which sends a notice to the coach if the patient doesn't follow the program or if something else happens. The back end also gives the caregiver feedback on the patient and how successful the treatment was.

The program is organised like this:

Week 1 - Sleep and CBT

The patient gets basic knowledge about sleep and sleep problems and evaluates the current sleeping situation (through self assessment) and set up targets before starting the main treatment.

Week 2 - Sleep restriction

The patient gets knowledge about sleep restriction and starts the treatment.

Week 3 - Strategies and problem solving

During the third week the patient gets help with strategies on how to get better sleep.

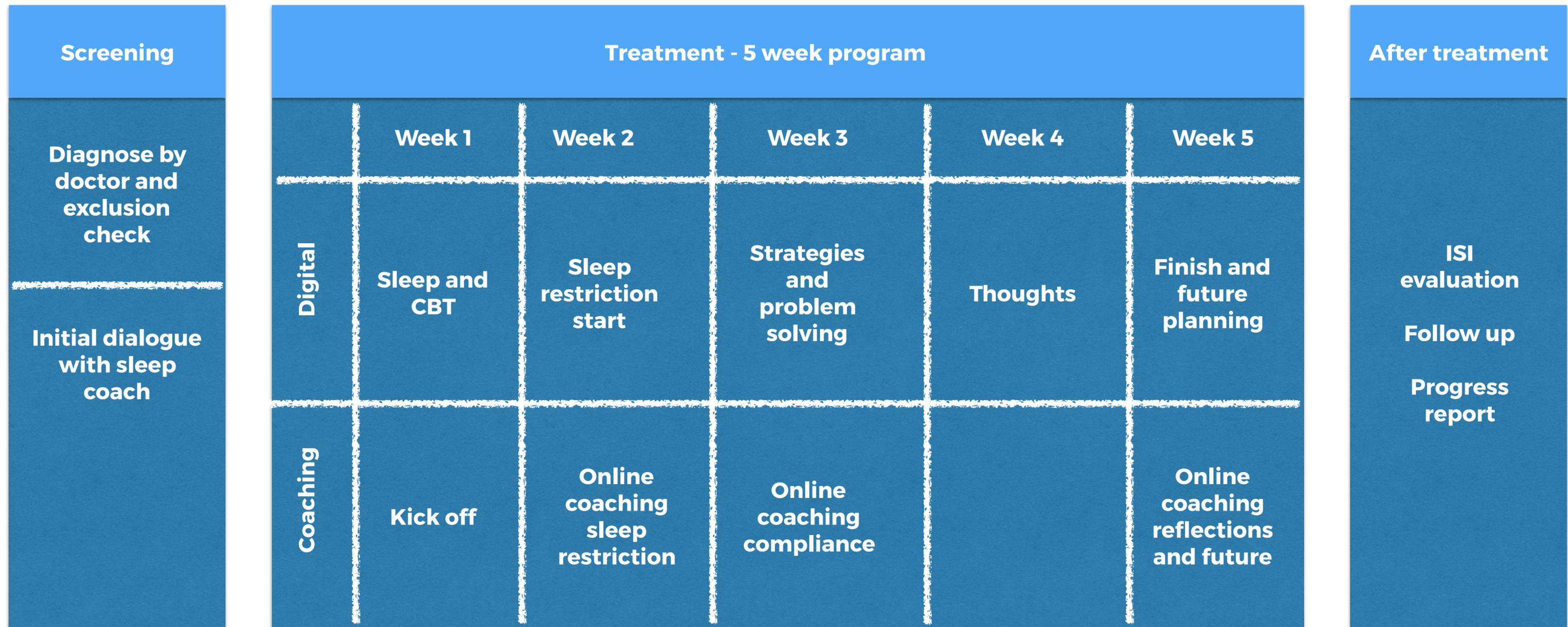
Week 4 - Thoughts

During this week we add the cognitive part of the treatment. The patient is trained in methods on how to handle negative thoughts based on CBT and how to relax in order to fall asleep. The patient also gets into the final phase of the sleep restriction.

Week 5 - Next steps and future

During the final week the patient summarises progress and makes a plan for the future in order to maintain good sleep.

PROGRAM OVERVIEW



EXPERTS BEHIND THE PROGRAM

Sleep Better is originally developed by Learning to Sleep, but the program has also been reviewed by external experts. The program is approved by the Swedish authority Läkemedelsverket as a medical device class A1 and is also CE-marked. The people behind Sleep Better are:

Helena Kubicek

Psychologist and one of Sweden's most prominent experts on sleep, often seen on Swedish TV and in newspapers about sleep and stress. She has also written several books on the theme sleep and stress.

Peter Boye

CBT therapist and cognitive researcher. Peter has studied people with sleeping problems for over 10 years and translated his therapy into digital solutions both for clinical use and for end consumers.

Micael Gustafsson

Serial entrepreneur and multimedia expert. Micael has been working with multimedia and e-learning solutions for over 15 years and has a great knowledge in how to move analog content into digital.



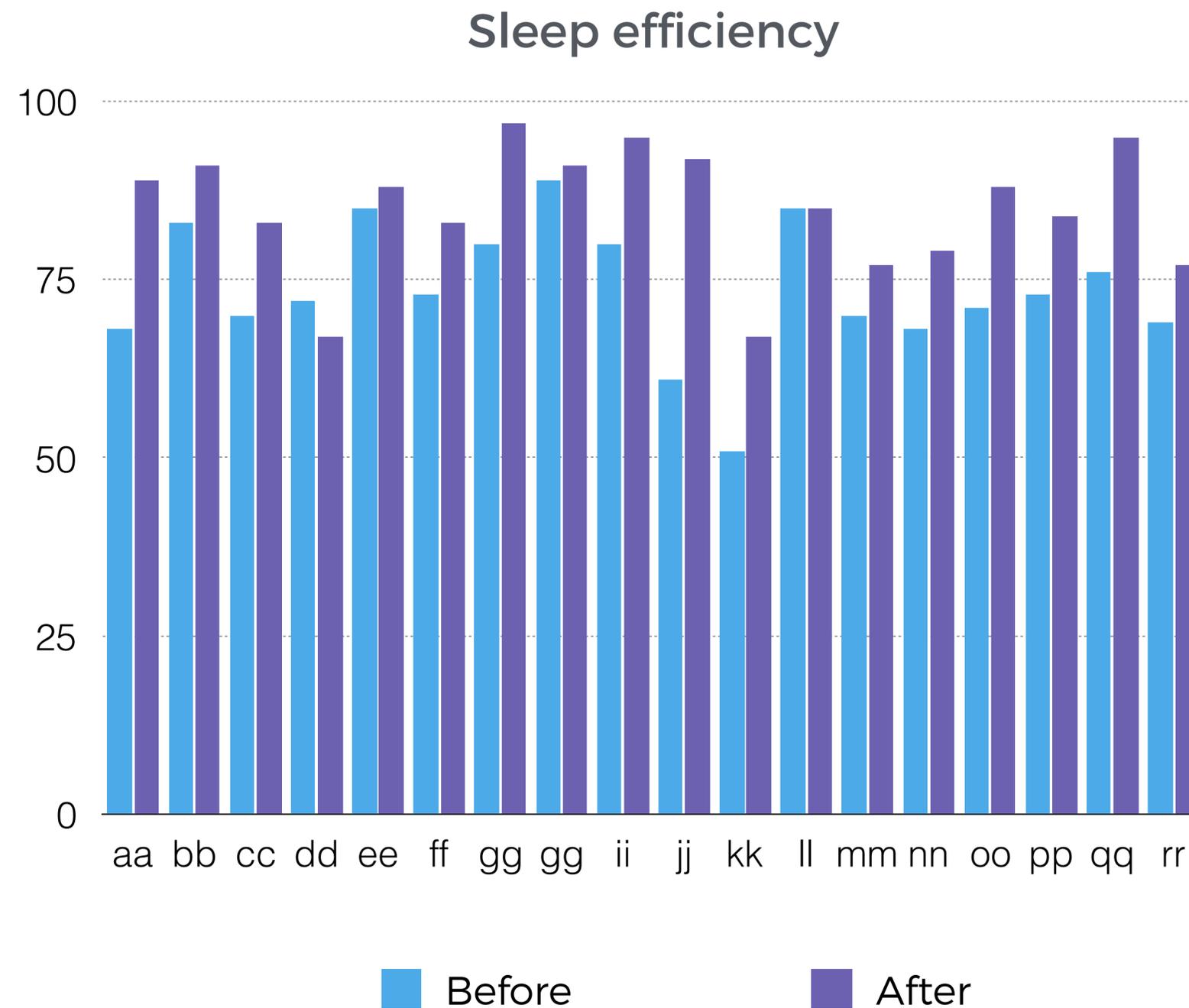
Helena Kubicek

PILOT STUDY

The pilot study was done in 2014 with 18 patients from the Swedish employer healthcare provider Previa. The pilot study was performed during fall and the results were followed up both directly after the program ended and a second time 12 weeks after the end of the program. Sleep quality was measured through self assessment by the individuals participating in the study and the main results from the study are:

Sleep efficiency

Out of the 18 patients, 17 got improved sleep efficiency. In average the efficiency **increased by 25 percent** during the program and 12 weeks after the treatment the improvement was still the same.



PILOT STUDY

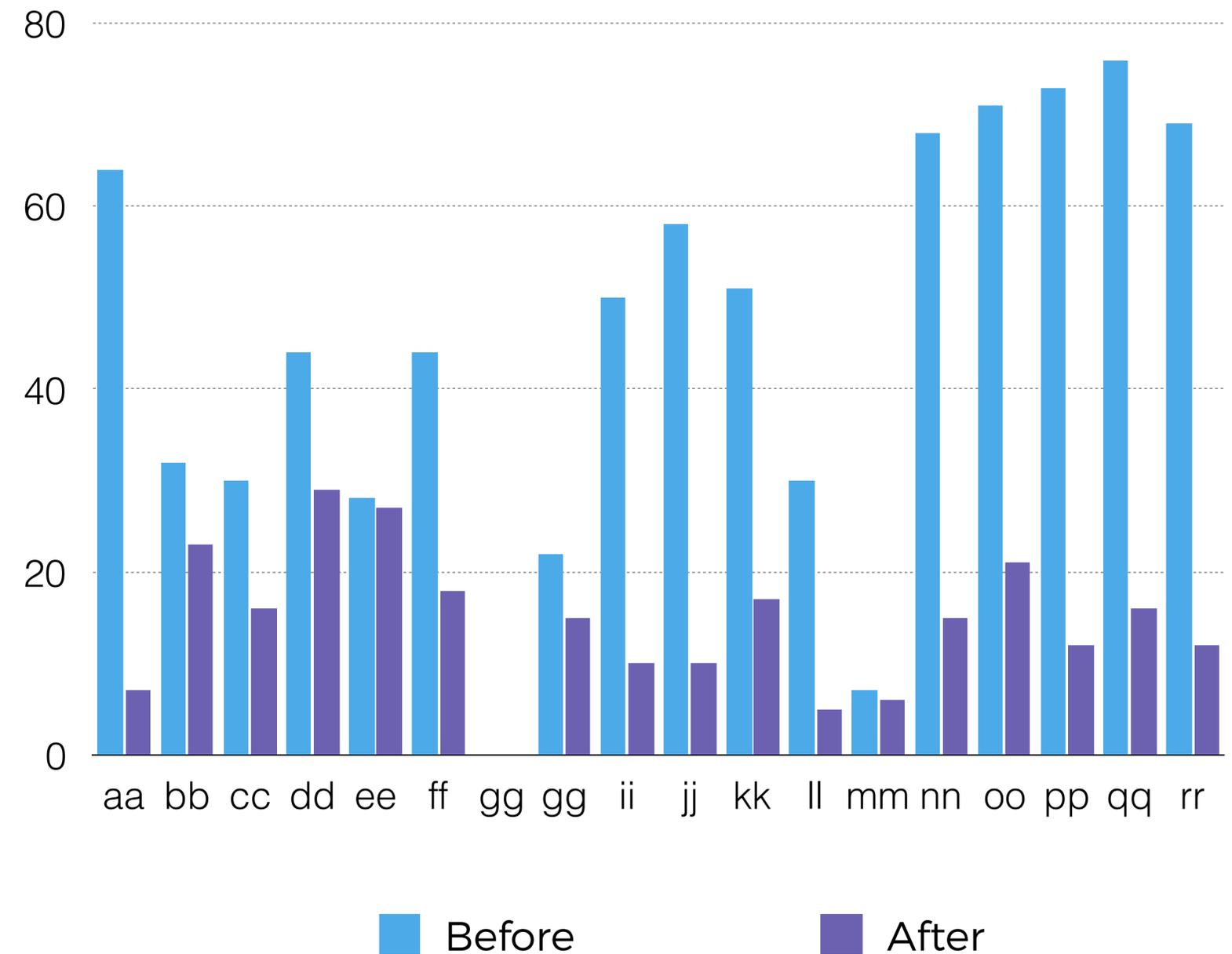
Time it takes to fall asleep

All patients reduced the time it took to fall asleep with **an average of 32 minutes**. The changes were persistent 12 weeks after the program ended.

Depression

Even though not part of the main sleep study we also measured the effects on depression on those patients who claimed they also suffered from depression from time to time. Out of 12 patients that claimed they were depressed, we could see that **60 percent** of them had positive impact on their depression after having fulfilled the program.

Time to fall asleep (minutes)



CLINICAL EVALUATION

The clinical evaluation was done during fall 2015 by Previa, in collaboration with Pfizer Sweden. The group of people participating consisted of 56 individuals in total and 54 of them completed the full program. All patients were diagnosed with Insomnia, i.e. they had a score on ISI (Insomnia Severity Index) that was over 15.

Screening and exclusion

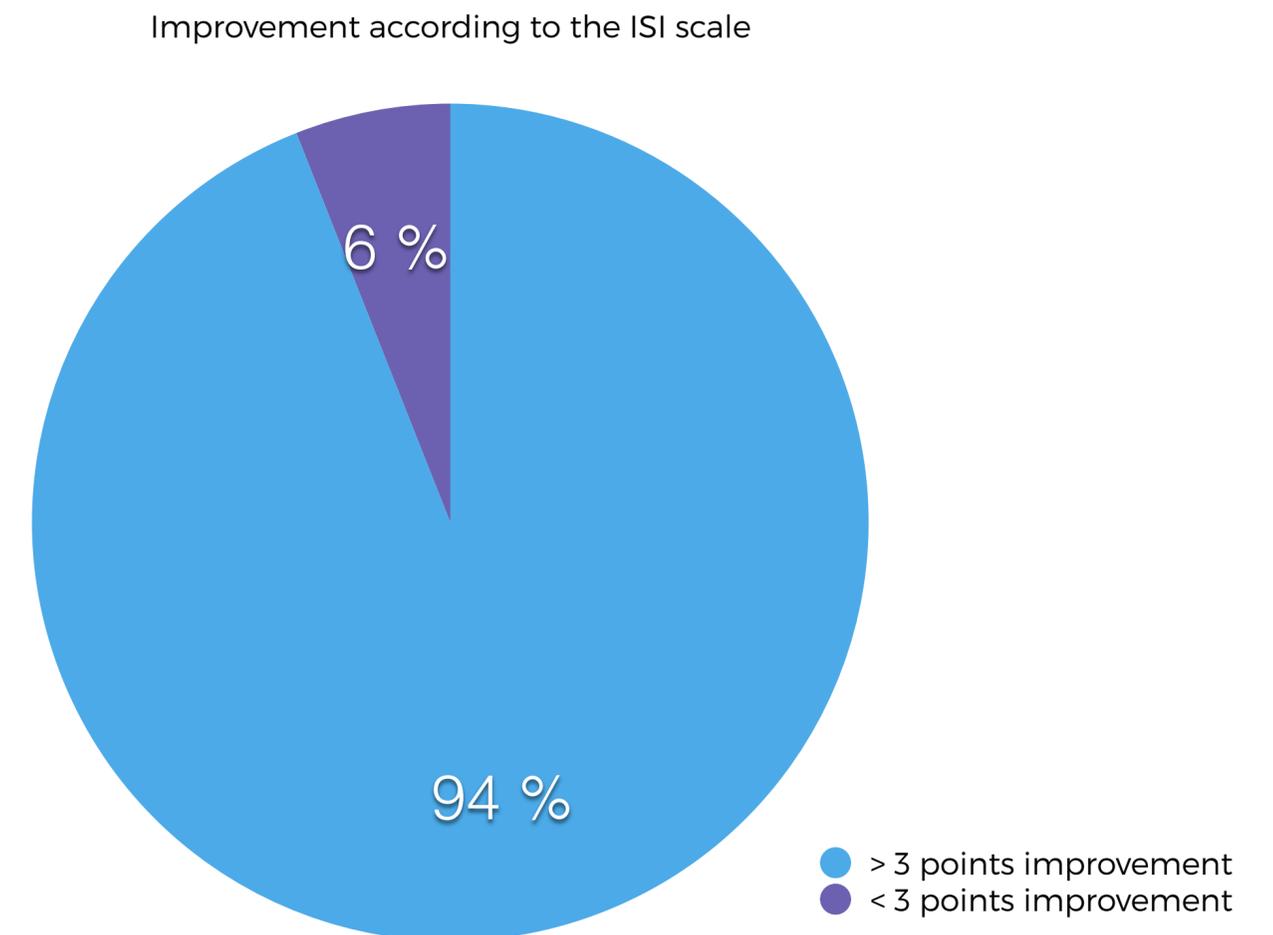
The patients went through a screening process that is recommended by Learning to Sleep. That includes a second ISI test in order to set a base line, and then an exclusionary screening in order to exclude patients that are not suitable for the treatment (including for instance untreated diabetes, The criteria can be found in appendix 1 and 2).

Evaluation period

The patients were recruited during summer 2015 and the first evaluation took place directly after treatment with a follow up 6 and 12 months after the treatment was completed. The results from the follow up was in general the same as the evaluation that was done directly after treatment.

Improvement of sleep

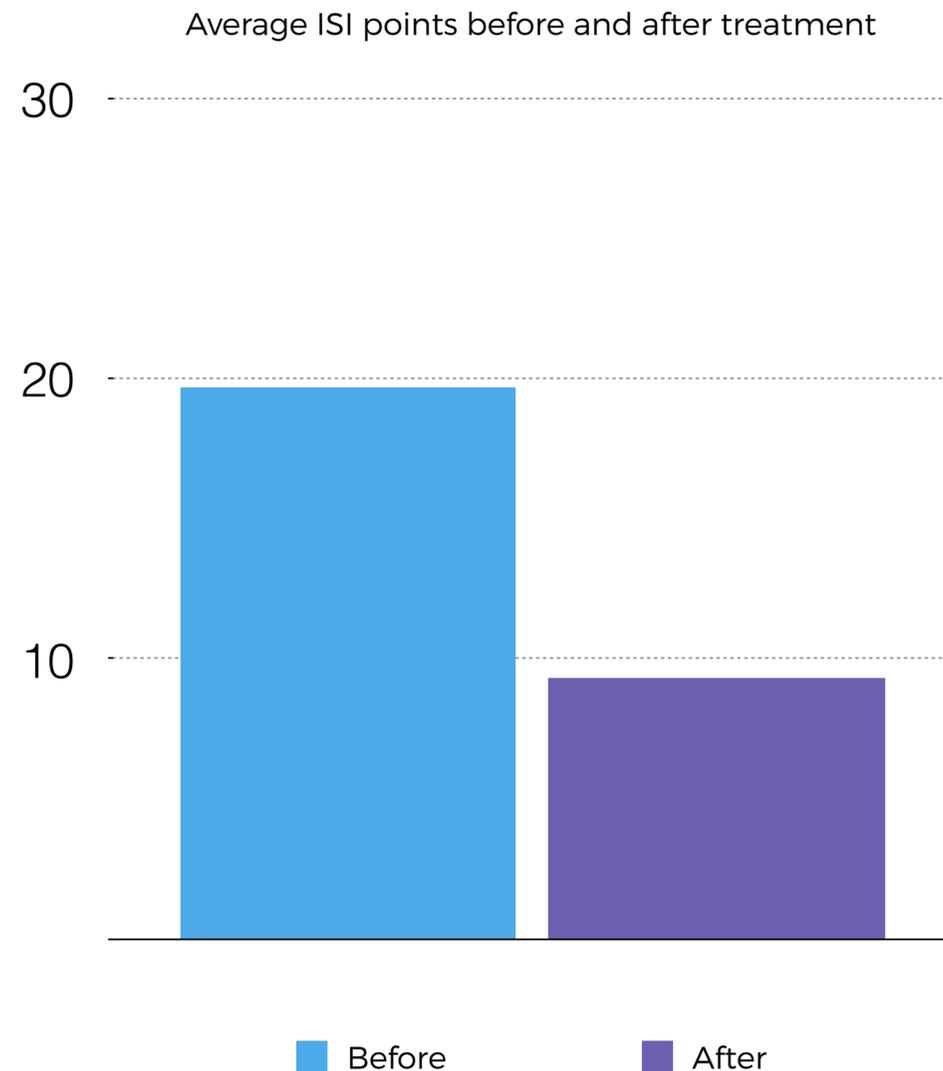
Out of the 54 patients participating **94 percent got improved sleep** which is, compared to traditional methods, a very good results. The study followed the recommendations from ISI specialists that says that an improvement of 3 points of more is a significant improvement of sleep.



CLINICAL EVALUATION

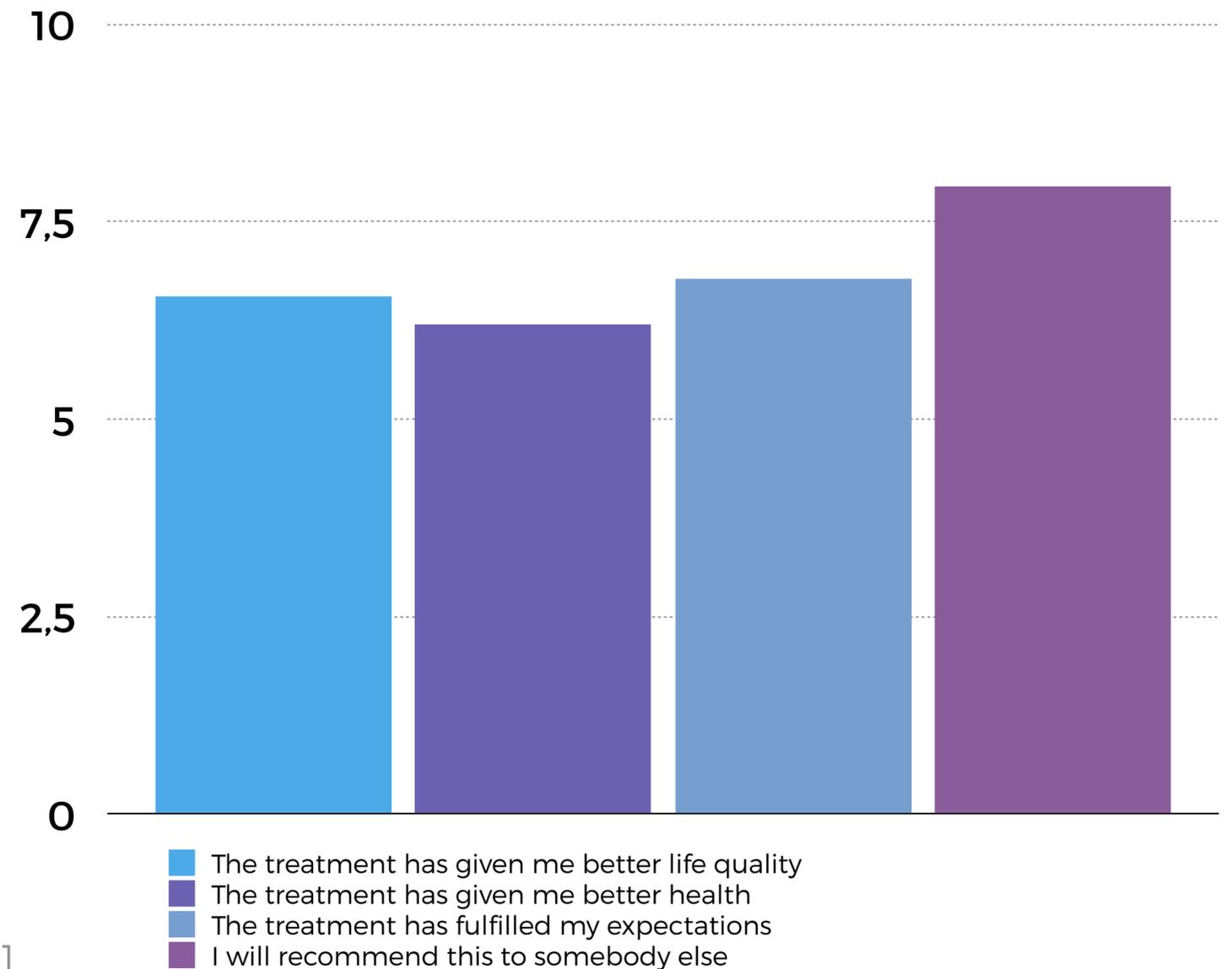
Average improvement of ISI

The ISI scale goes from 0 to 30 and people with a score over 15 are diagnosed with Insomnia. In average Sleep Better **improved ISI with 10.4 points** after the 5 week treatment.



Patient evaluation

Besides the clinical evaluation the patients also completed a survey regarding their general experience with the treatment.



References

- Benedict, Acute sleep deprivation reduces energy expenditure in healthy men¹⁻⁴, *The Journal of Clinical Endocrinology & Metabolism*, April 6, 2011.
- Culpin & Whelan, The wake-up call for sleepy managers, *The Ashridge Journal*, Spring 2009.
- Cheng, Computerised cognitive behavioural therapy for insomnia: a systematic review and meta-analysis, *Psychother Psychosom*. 2012;81(4): 206-16. Epub 2012 May 11.
- Darien, IL, The good life: Good sleepers have better quality of life and less depression, *American Academy of Sleep Medicine*, June 15, 2011.
- D. Payne, et al, Sleep Makes Your Memories Stronger, and Helps With Creativity, *Science Daily* Dec. 17, 2010
- Ekstedt M, Söderström M, Åkerstedt T. Sleep physiology in recovery from burnout. *Biological Psychology* 2009;82:267-273.
6Bilaga 1 2009-12-22-
- Hetta, Psykiatri sydväst, Sömnstörningar, Karolinska Universitetssjukhuset, Stockholm Åke Schwan, Landstingets läkemedelsenhet, Uppsala
- Maddox, W. T. et al, The Effects of Sleep Deprivation on Information-Integration Categorization Performance, *SLEEP* 2009;32(11):1439-1448
- Morin CM, Bootzin RR, Buysse DJ, Edinger JD, Espie CA, Lichstein KL. Psychological and behavioral treatment of insomnia: update of the recent evidence (1998-2004). *Sleep* 2006;29:1398-1414
- SBU. Behandling av sömnbesvär hos vuxna. En systematisk litteraturöversikt. Stockholm: Statens beredning för medicinsk utvärdering (SBU); 2010. SBU-rapport nr 199
- Seung-Schik Yoo¹The human emotional brain without sleep a prefrontal amygdala disconnect, *Current Biology*, Volume 17, Issue 20, R877-R878, 23 October 2007
- Silber MH. Clinical Practice. Chronic insomnia. *N Engl J Med*. 2005;353:2827
- Sundbom, et al, Asthma symptoms and nasal congestion as independent risk factors for insomnia in a general population: results from the GA2LEN survey, *Allergy*, February 2013, Volume 68, Issue 2, pages 213-219
- Sonnenschein M, Vorbi MJ, Verbraak MJPM, Schaufeli WB, Maas CJM, van Doornen LJP. Influence of sleep on symptom improvement and return to work in clinical burnout. *Scand J Work Environ Health* 2008;34:23-32
- Åkerstedt T. Sömn som återhämtning efter stress. *Läkartidningen* 2004;101:1501-1505



LEARNING
TO SLEEP

Stora Varvsgatan 6 A SE-211 19 Malmö, (HQ)
The Park, Hälsingegatan 49, 113 31, Stockholm
Nordic Innovation House, 470 Ramona St, Palo Alta CA94301, USA
www.learningtosleep.se