



The Proof-of-Principle Study



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Tobacco consumption

Tobacco consumption is the **leading preventable cause** of premature mortality worldwide.



Further PDF documents

- **The scientific background**
<https://www.luna-medical.com/en/scientific/>
- **The proof-of-principle study**
<https://www.luna-medical.com/en/pop-study/>
- **The patent**
<https://www.luna-medical.com/en/patent/>
- **Cooperations with companies**
<https://www.luna-medical.com/en/companies/>
- **Cooperations with health insurance funds**
<https://www.luna-medical.com/en/health-insurance/>
- **Cooperations with pharmaceutical companies**
<https://www.luna-medical.com/en/pharmaceuticals/>
- **The covered need - Quit smoking "now"**
<https://www.luna-medical.com/en/covered-need/>
- **The enormous healthcare gap - Smoke "less" first**
<https://www.luna-medical.com/en/healthcare-gap/>
- **Smoking - A global overview**
<https://www.luna-medical.com/en/global-overview/>

1. Differentiation: "Covered need" vs. "CiQuit"

The problem

There is a lack of a practical **reduction program** that leads to complete smoke-free status.

The offering must drastically reduce the physical and mental dependence on **cigarettes**.

Quit smoking "now"!

Many offers of help = Crowded market



One goal

Abstinence: Yes or No
Desirable

Switch: Yes or No
Criticism: Harmful to health,
dual smoking, protection of minors,
banned in some countries.*

Only - **around 10%** - of smokers attempt to quit smoking each year or try switching to alternative products.*

There are many support options available for the **desirable complete smoking cessation**, such as nicotine replacement therapy, medication, courses, hypnosis, acupuncture, apps, and more. **Despite all the offers of help, the relapse rates are immense!***

= **Covered need**

Smoke "less" first!

The enormous healthcare gap



Several goals:

- Significant reduction
- Improvement of life quality as a smoker
- **Building motivation and optimal preparation for quitting smoking**

The majority of smokers - **around 60%** - want to reduce their consumption before quitting smoking.

From a medical perspective, the program must not only enable a significant reduction but also specifically prepare the body and mind for smoking cessation.

It must reactivate the ability to abstain and effectively motivate towards quitting smoking.

= **Uncovered need**

What addiction experts say!

"Reduction treatments ...

... are aimed at people who are willing to change but are unable or unwilling to lead an abstinent lifestyle. Various field studies, randomised control group studies and meta-analyses have shown

that significantly more people are willing to reduce than to abstain ..."¹

*Prof. Dr. Joachim Körkel u. Matthias Nanz,
The paradigm of open-ended addiction work, 2016,*

USP:

Smoke "less" first!

Reaches smokers!

> Psychological background: **Rubicon model**

See Worth knowing:

7. CiQuit - Rubicon model: The quick decision to use

2. Our offer for the majority of smokers!

The solution

Stepwise **reconditioning** of smoking behavior by unlearning the mental and physical dependency.

Using a proven **milestone approach** towards a **smoke free life**.



What addiction experts say!

"Smokers who are addicted to tobacco can hardly imagine quitting smoking immediately.

They can only imagine quitting smoking by reducing the cigarette consumption step by step."

*Prof. Dr. Robert Olbrich,
Otto Selz Institute for Applied Psychology*

Reconditioning with CiQuit-Box and CiQuit-App



For a detailed explanation see:
www.luna-medical.com/en/scientific



The reduction of smoking ...

- ... increases the likelihood of a future attempt to stop smoking.
- ... strengthens the patient's confidence in their ability to stop smoking completely and increase the number of quit attempts per year.
- ... ***reduces at least some of the risks associated with smoking.**¹

1) Source: https://ensp.network/wp-content/uploads/2020/10/guidelines_2020_english_forprint.pdf | S. 91 ff

2) Source: <https://www.google.com/search?q=20.+t%C3%BCbinger+suchttherapie+2015+suchttherapie+im+wandel+der+letzten+zwei+jahrzehnte+client>

3. Primary problem and solution

From **reconditioning** to abstinence!



For a detailed explanation see:
www.luna-medical.com/en/scientific

Previous treatment approach

- Medical help



Weaken the effects of nicotine withdrawal

- Psychological help



- Hypnosis
- Acupuncture
- Books
- Apps
- Online courses and much more

Overcome the effects of nicotine withdrawal

For a detailed explanation see:
www.luna-medical.com/en/covered-need

Problem
Quit smoking with
inability to abstain

Inability to
abstain



Psychological (mental)
dependence +
Physical (bodily)
dependence

Addiction centre

Effects of nicotine withdrawal "Hungry nicotine receptors"

- Agonizing craving
- Irritability and restlessness
- Frustration and anger
- Anxiety
- Sleep disorders
- Concentration disorders
- Decreased heart rate
- Increased appetite and weight gain



Quelle: J. Henningfield

High level of suffering

High relapse rates (despite help)

Next attempt to quit smoking is usually
postponed for years

Solution
Quit smoking with
ability to abstain

CiQuit®

Goal 3

Ability to
abstain



~~**Psychological** (mental)
dependence +
Physical (bodily)
dependence~~

Addiction centre

Effects of nicotine withdrawal "Hungry nicotine receptors"

Greatly weakened!
At best, no longer
available.



Quelle: J. Henningfield

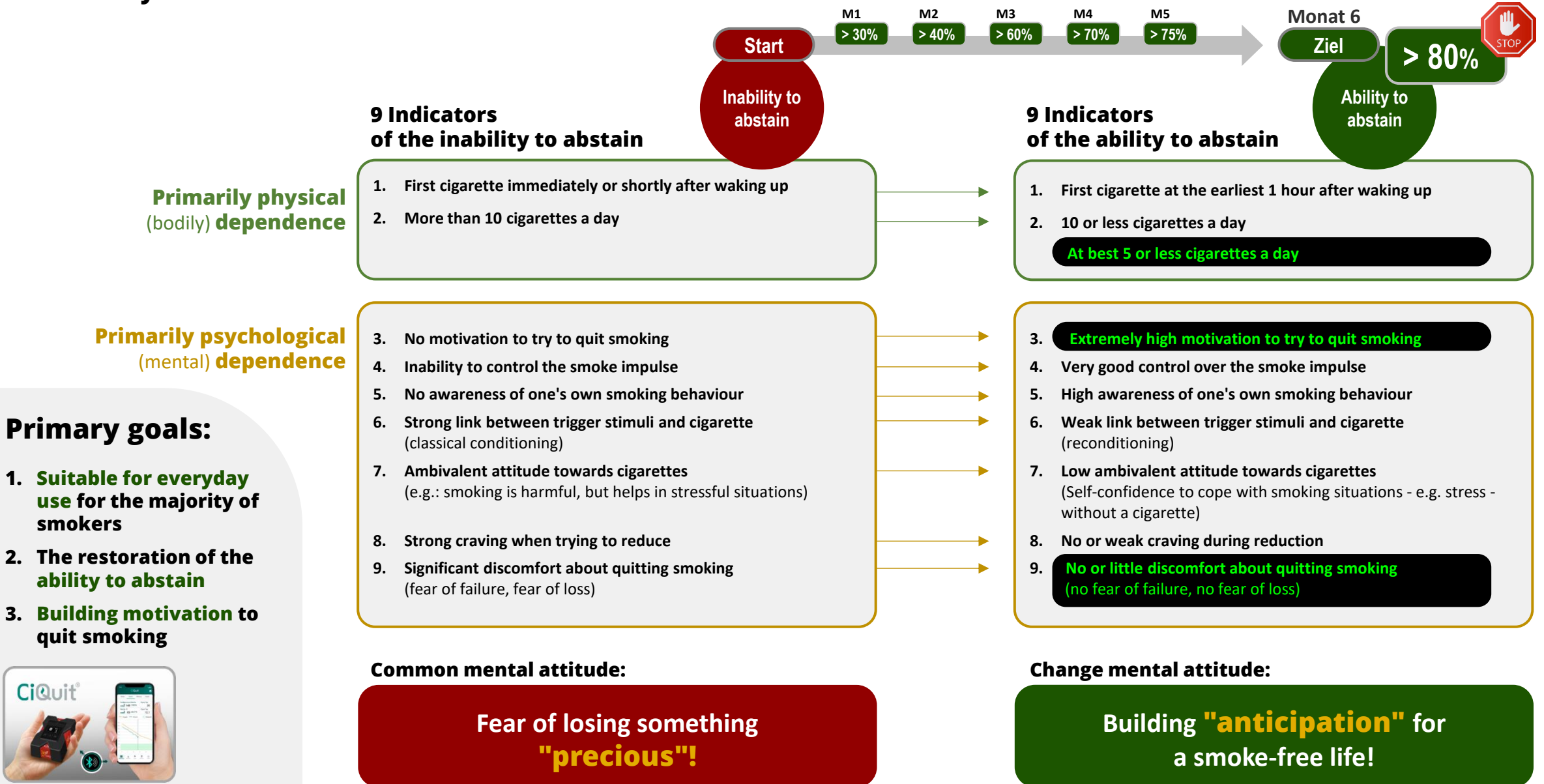
No or low level of suffering

High success rates*

In case of relapse, return to CiQuit with
low consumption

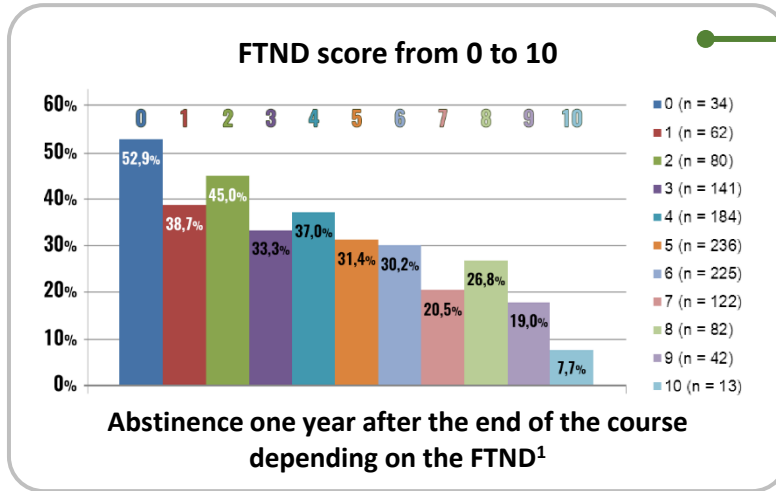
*Sub-goals: Strong reduction, quality of life, motivation to quit smoking + outcome goal: abstinence

4. The 9 key indicators



5. CiQuit and the scientific derivation

CiQuit in the context of the Fagerstrom Test (FTND)*



Result:

The lower the **physical dependence**, the more likely the participant is to be a non-smoker one year after the end of the course.²



CiQuit
Treatment of the **physical and mental** indicators of the inability to abstain

Psychological dependence

The additional treatment of psychological tobacco addiction is crucial, as it addresses the core of the addiction and thus enables a sustainable cessation and overcoming of the addiction (ability to abstain).

CiQuit® Goals

Ability to abstain

> 80%



1. First cigarette at the earliest 1 hour after waking up
2. 10 or less cigarettes a day

At best 5 or less cigarettes a day

3. **Extremely high motivation to try to quit smoking**
4. Very good control over the smoke impulse
5. High awareness of one's own smoking behaviour
6. Weak link between trigger stimuli and cigarette (reconditioning)
7. Low ambivalent attitude towards cigarettes (Self-confidence to cope with smoking situations - e.g. stress - without a cigarette)
8. No or weak craving during reduction
9. **No or little discomfort about quitting smoking (no fear of failure, no fear of loss)**



"Success rates of a German-speaking, cognitive-behavioral group program for tobacco cessation considering the FTND"

The Fagerstrom Test for Nicotine Dependence (FTND) primarily takes **physical dependence** into account, as 8 out of 10 possible points relate to (early) morning smoking and cigarette consumption.

* The FTND (6 items) is a standard instrument for assessing the intensity of **physical dependence** to nicotine.³ The higher the score on the FTND, the lower the likelihood of a successful, lasting smoking cessation.

How soon after you wake up do you smoke your first cigarette?

Score points

- (3) Within 5 minutes
- (2) 6 - 30 minutes
- (1) 31 - 60 minutes
- (0) After 60 minutes

How many cigarettes per day do you smoke?

Score points

- (3) 31 or more
- (2) 21 - 30
- (1) 11 - 20
- (0) 10 or less

Which cigarette would you hate most to give up?

(1) The first one in the morning (0) Any other

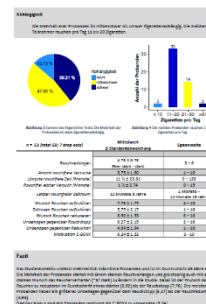
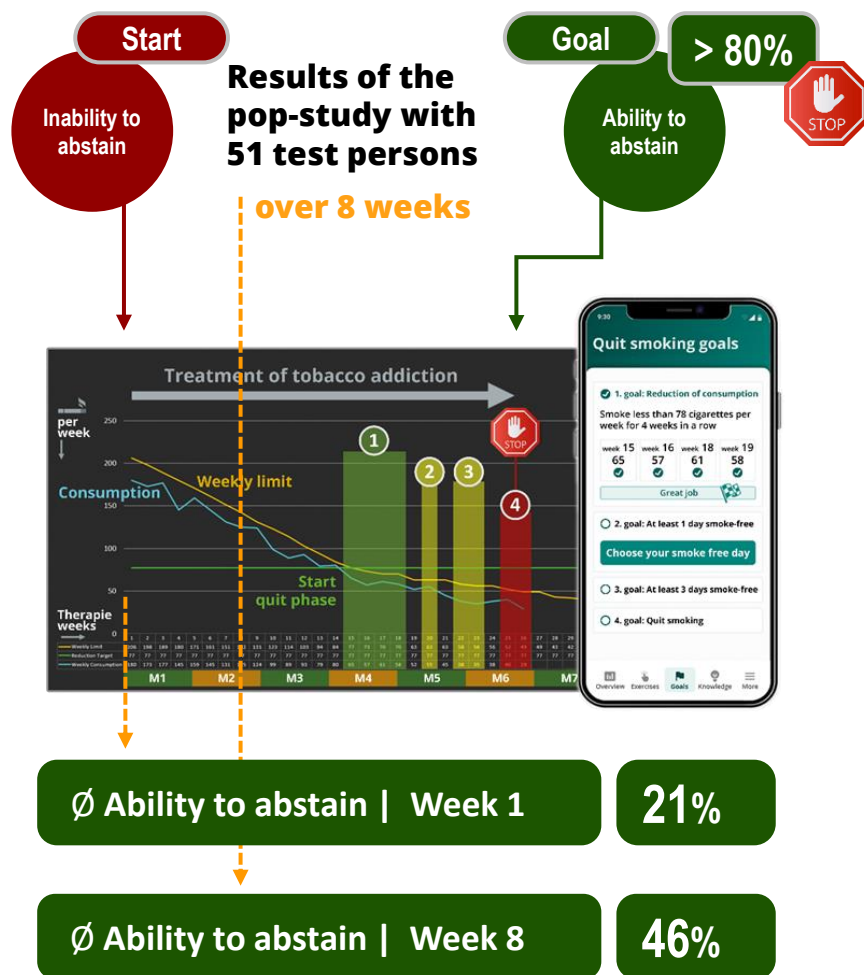
Do you smoke more frequently during the first hours after waking than during the rest of the day? (1) Yes (0) No

Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema)? (1) Yes (0) No

Do you smoke when you are so ill that you are in bed most of the day? (1) Yes (0) No

1) Source: https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/5_Publikationen/Drogen_und_Sucht/Berichte/Projektbericht_Effektivitaet_von_Tabakentwoehnung_in_Deutschland.pdf | p. 59
2) Source: https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/5_Publikationen/Drogen_und_Sucht/Berichte/Projektbericht_Effektivitaet_von_Tabakentwoehnung_in_Deutschland.pdf | p. 60
3) Source: <https://elcentro.sonhs.miami.edu/research/measures-library/ftnd/index.html>

6. Study Objective, Study Population and Results



Study collective

- 51 regular starters and 51 regular finishers

Gender:

36m 70,5% | 11w 21,6% | 4d 7,8%

Age:

29 = 1 TP 2,0% | 30-39 = 12 TP 23,5% | 40-49 = 12 TP 23,5% | 50-59 = 17 TP 33,3% | 60-68 = 9 TP 17,6%

- Tobacco dependence according to Fagerström (FTND):**
low 0-2 = 4 TP 7,8% | medium 3-4 = 12 TP 23,5% | strong 5-6 = 11 TP 21,6% | very strong 7-10 = 20 TP 39,2%
- study period: 8 weeks
- Inclusion: At least 10 cigarettes per day

51 test persons (TP)

Start

10 cigarettes a day

2 TP = 4%

11 to 20 cigarettes a day

33 TP = 65%

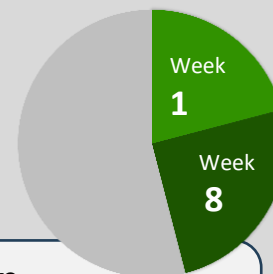
21 to 30 cigarettes a day

14 TP = 27%

31 cigarettes a day

2 TP = 4%

The primary objective of the pilot study was to investigate the effect of CiQuit on the **ability to abstain** of smokers.



Overall evaluation

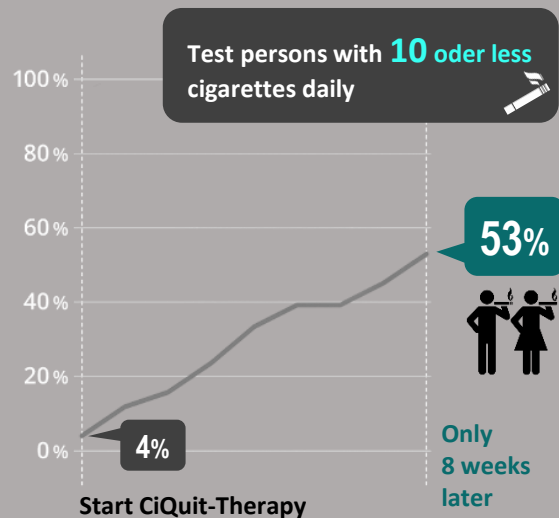
		Week 1	Week 8	
Ability to abstain	21%	46%		
Inability to abstain	79%	54%		
Quit smoking	21%	46%		
At least 1 day smoke-free	21%	46%		
At least 3 days smoke-free	21%	46%		
At least 1 week smoke-free	21%	46%		
At least 2 weeks smoke-free	21%	46%		
At least 3 weeks smoke-free	21%	46%		
At least 4 weeks smoke-free	21%	46%		
At least 5 weeks smoke-free	21%	46%		
At least 6 weeks smoke-free	21%	46%		
At least 7 weeks smoke-free	21%	46%		
At least 8 weeks smoke-free	21%	46%		
At least 9 weeks smoke-free	21%	46%		
At least 10 weeks smoke-free	21%	46%		
At least 11 weeks smoke-free	21%	46%		
At least 12 weeks smoke-free	21%	46%		
At least 13 weeks smoke-free	21%	46%		
At least 14 weeks smoke-free	21%	46%		
At least 15 weeks smoke-free	21%	46%		
At least 16 weeks smoke-free	21%	46%		
At least 17 weeks smoke-free	21%	46%		
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At least 20 weeks smoke-free	21%	46%		
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At least 24 weeks smoke-free	21%	46%		
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At least 31 weeks smoke-free	21%	46%		
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At least 34 weeks smoke-free	21%	46%		
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At least 91 weeks smoke-free	21%	46%		
At least 92 weeks smoke-free	21%	46%		
At least 93 weeks smoke-free	21%	46%		
At least 94 weeks smoke-free	21%	46%		
At least 95 weeks smoke-free	21%	46%		
At least 96 weeks smoke-free	21%	46%		
At least 97 weeks smoke-free	21%	46%		
At least 98 weeks smoke-free	21%	46%		
At least 99 weeks smoke-free	21%	46%		
At least 100 weeks smoke-free	21%	46%		

Indicator: More than 10 cigarettes a day

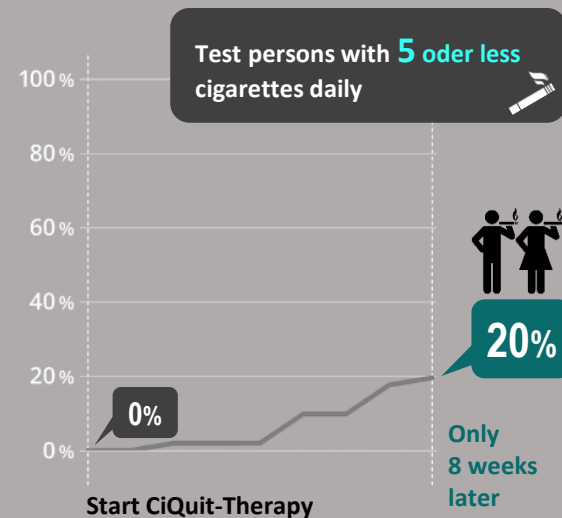
Goal: 10 or less cigarettes a day

At best 5 or less cigarettes a day

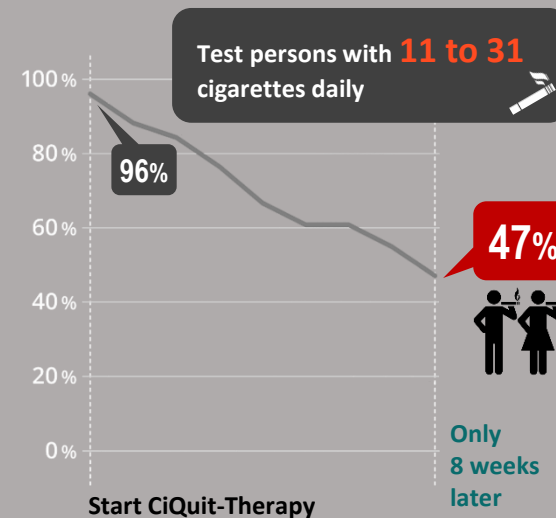
Example indicator: Reduction



Example indicator: Reduction



Example indicator: Reduction



Note:

It is particularly noteworthy that 10 out of 51 participants (20%) were already smoking 5 or less cigarettes per day after 8 weeks.

Start CiQuit therapy
51 test persons smoked
per week

6.685

Average
per day

18,7

Average monthly costs
for cigarettes
around € 230

Only 8 weeks later

51 test persons smoked per
week

3.962

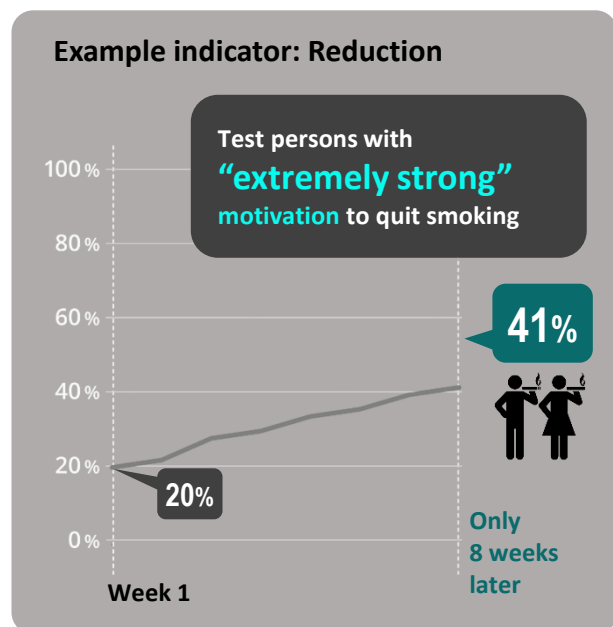
Average
per day

11,1

Average monthly costs
for cigarettes
around € 137

Indicator: No motivation to try to quit smoking

Goal: Extremely high motivation to try to quit smoking



How motivated are you currently to seriously quit smoking completely?

Answer Alternatives

	1	2	3	4	5	6	7	8	9	10
	Extremely strong to rather strong					rather not to not at all				
After week 1	20%	10%	8%	10%	37%	14%	0%	2%	0%	0%
Only 8 weeks later	41%	8%	2%	4%	27%	12%	2%	2%	0%	2%

Note:

It should be emphasized that every week more participants responded with "extremely strong" (1) regarding their motivation to stop smoking. In week 8, this was already 21 (41%) of 51 participants.

Indicator: Inability to control the urge to smoke**Goal:** Very good control over the smoke impulse

Example indicator: Control

Test persons with:
I fully agree!

0.0 %

After
week 1

43.1 %

Only
8 weeks
later

I can control my smoke impulse very well!

Answer Alternatives

	I fully agree!	I tend to agree!	I tend to disagree!	I disagree!
After week 1	0%	14%	84%	2%
Only 8 weeks later	43%	31%	14%	12%

Note:

After week 1, none of the test persons selected the alternative answer "I fully agree" (0%). It is interesting to note that after 8 weeks, 22 test persons had already selected "I fully agree" (43%).

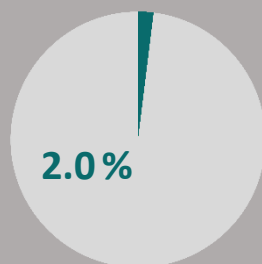
Indicator: No awareness of one's own smoking behaviour

Goal: High awareness of one's own smoking behaviour

Example indicator: Awareness

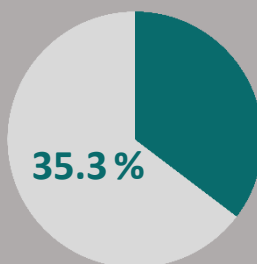


Test persons with:
„extremely strong“
and „very strong“



2.0%

After
week 1



35.3%

Only
8 weeks
later

How much are you paying attention to your smoking behaviour at the moment?

Answer Alternatives

	1	2	3	4	5	6	7	8	9	10
	extremely strong to rather strong					rather not to not at all				
After week 1	2%	0%	4%	8%	29%	31%	2%	6%	6%	12%
Only 8 weeks later	20%	16%	8%	18%	18%	18%	2%	0%	0%	2%

Note:

It should be highlighted that the proportion of test persons who answered "extremely strong" and "very strong" (1 and 2) rose from 2.0% in week 1 to 35.3% in week 8.

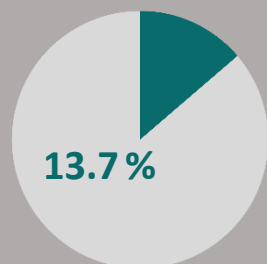
Indicator: Strong link between trigger stimuli and cigarette (classical conditioning)

Goal: Weak link between trigger stimuli and cigarette (reconditioning)

Example indicator: Awareness

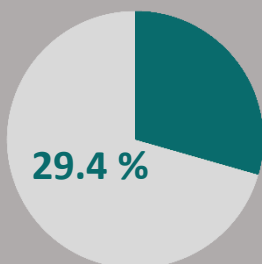


Test persons with:
I fully agree!



13.7 %

After
week 1



29.4 %

Only
8 weeks
later

The box helps me to decouple previous smoking situations from the cigarette!

Antwort Alternativen

	I fully agree!	I tend to agree!	I tend to disagree!	I disagree!
After week 1	14%	39%	35%	12%
Only 8 weeks later	29%	41%	12%	18%

Note:

As early as week 1, around 14% of participants voted "I fully agree!".

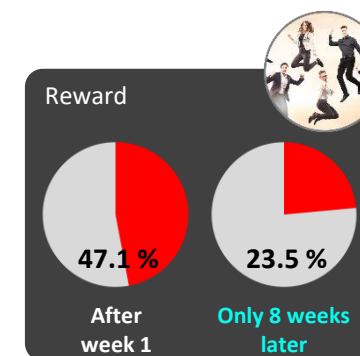
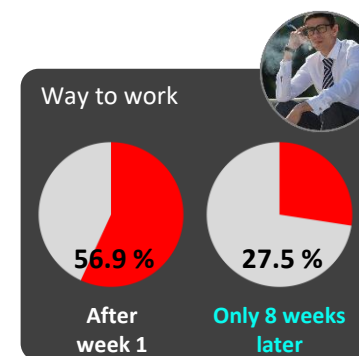
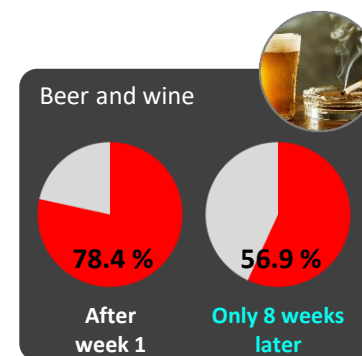
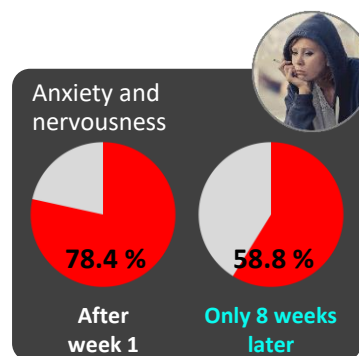
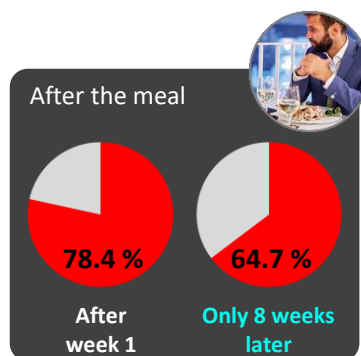
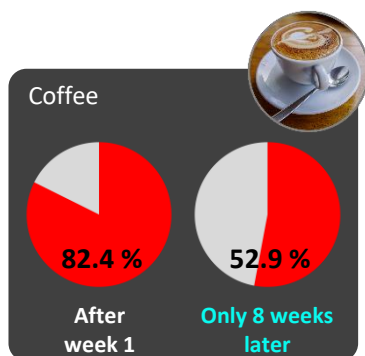
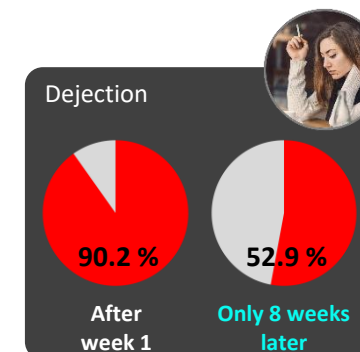
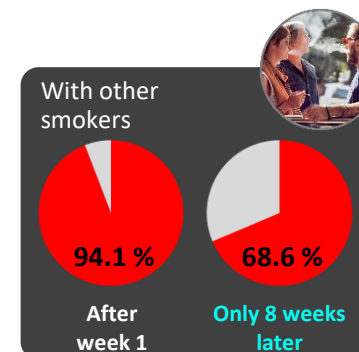
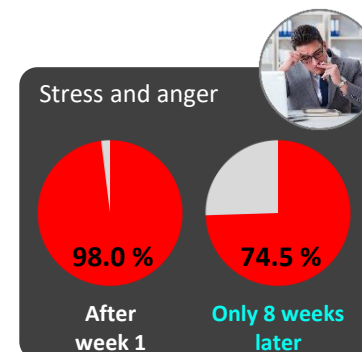
In week 8, this proportion had already more than doubled to around 29%.

Indicator: Ambivalent attitude towards cigarettes (e.g.: smoking is harmful, but helps in stressful situations)

Goal: Low ambivalent attitude towards cigarettes (Self-confidence to cope with smoking situations - e.g. stress - without a cigarette)

How strong is your current craving for cigarettes in the following situations?

No craving	☐	Stronger	☐
Minimal	☐	Strong	☐
Low	☐	Very strong	☐

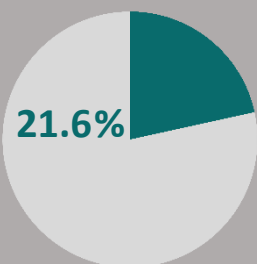
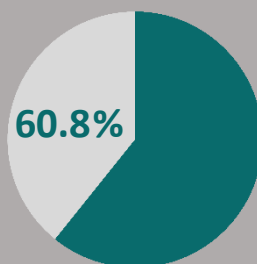


Note:

After 8 weeks of using CiQuit, the urge to smoke was significantly reduced in all smoking situations.

Indicator: Strong craving during reduction**Goal: No or weak craving during reduction**

Example indicator: Craving during reduction

Test persons with:
"not at all" to "rather little"After
week 1Only
8 weeks
later

How strong would you rate your craving for cigarettes in the last 3 days?

Answer alternatives

	not at all	little	rather little	rather strong	strong	very strong
After week 1	0%	4%	18%	57%	20%	2%
Only 8 weeks later	4%	12%	45%	27%	10%	2%

Note:

In the 1st week, around 22% of the test persons answered "not at all" to "rather little" regarding the craving for cigarettes. Despite a permanent reduction, this figure was **increased to around 61% after week 8.**

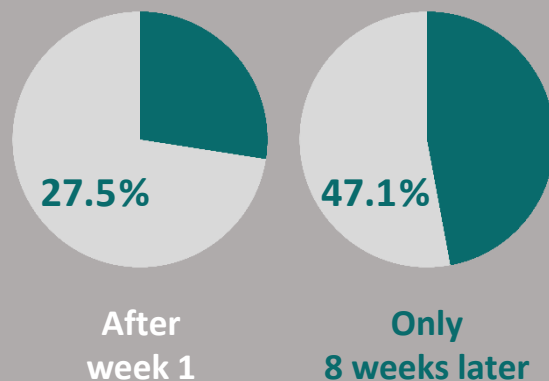
Indicator: Significant discomfort about quitting smoking (fear of failure, fear of loss)

Goal: No or little discomfort about quitting smoking (no fear of failure, no fear of loss)

Example indicator: Discomfort quitting



Test persons with:
"not at all" to "rather not"



How much discomfort do you currently feel about quitting smoking completely?

Answer alternatives

	1	2	3	4	5	6	7	8	9	10
	not at all to rather not					rather strong to extremely strong				
After week 1	0%	6%	6%	2%	14%	39%	10%	6%	4%	14%
Only 8 weeks later	10%	6%	8%	4%	20%	29%	12%	2%	6%	4%

Note:

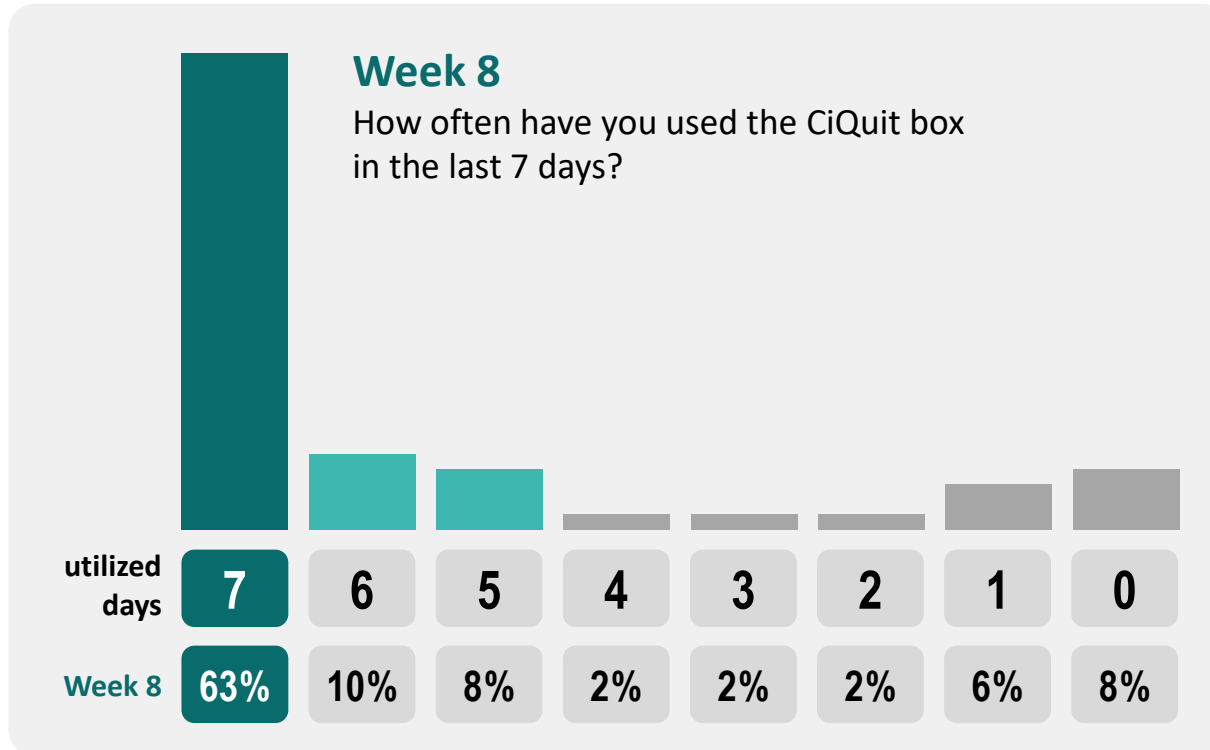
The discomfort about quitting smoking has decreased.

Whereas in week 1 only 14 test persons (27.5%) chose the answer alternatives 1 to 5, by week 8 this figure had risen to 24 test persons (47.1%).

In particular, the extreme answer alternatives (1 and 10) developed positively.

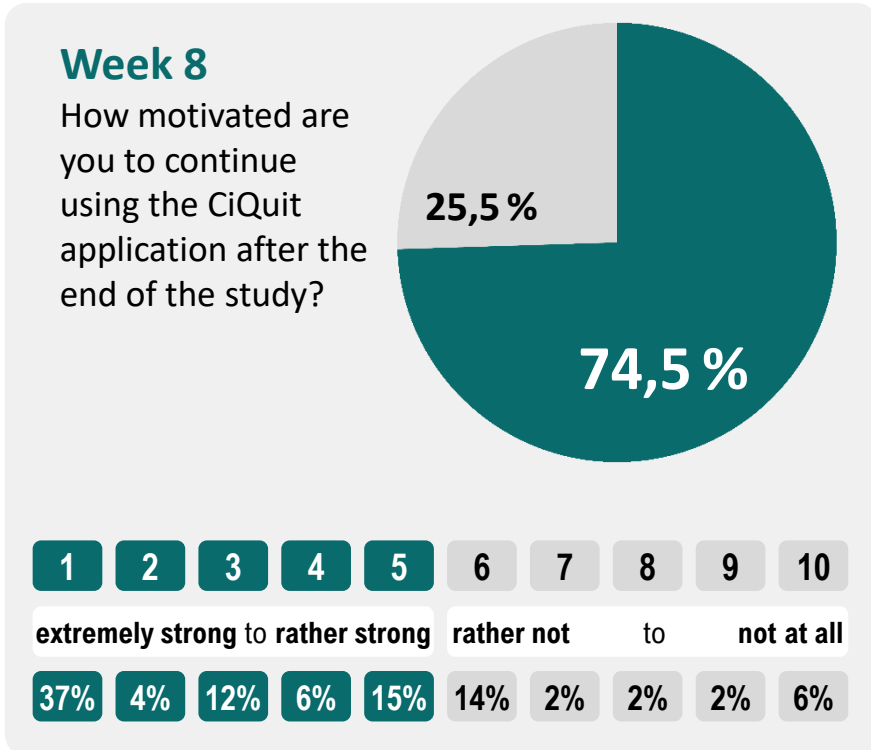
51 test persons | after 8 weeks

Adherence

**Note:**

Some smokers who have already reduced their daily consumption average to 5 or fewer cigarettes may no longer smoke at all on some days of the week.

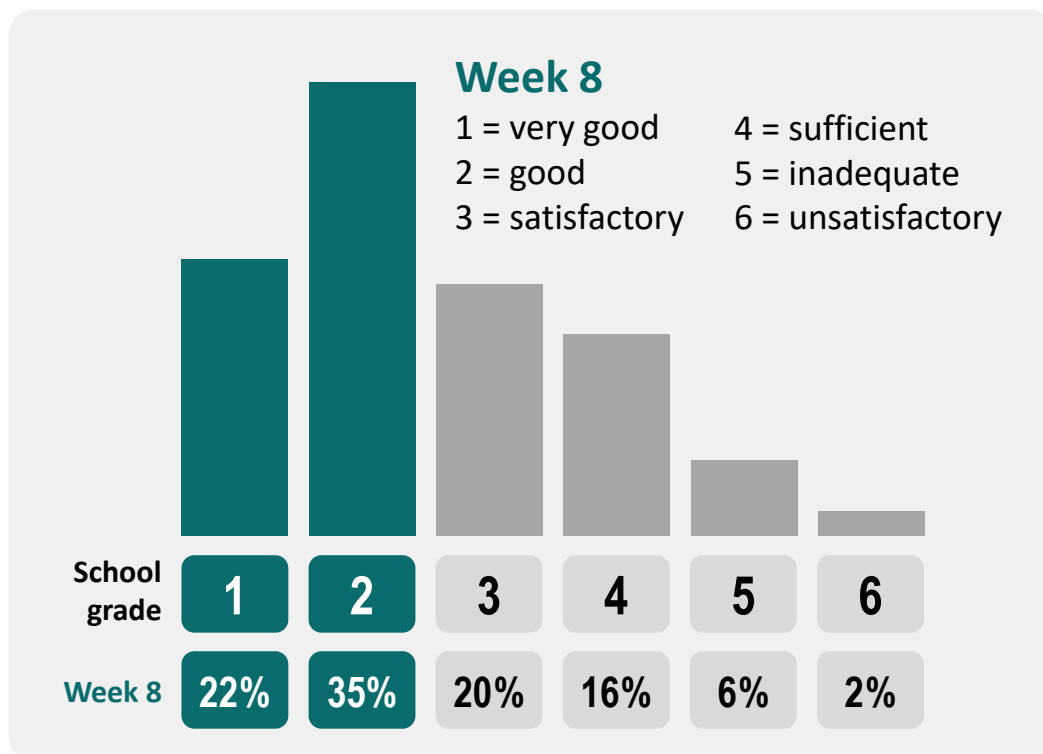
Further use after study

**Note:**

Some smokers who have already reduced their daily consumption average to 5 or fewer cigarettes may want to quit smoking altogether.

51 test persons | after 8 weeks

Grading



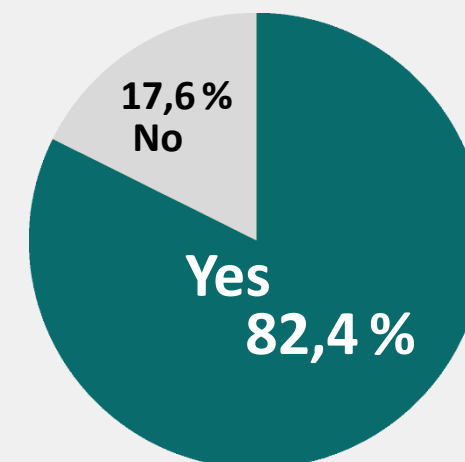
Note:

The application left a "very good" to "good" overall impression on 57% of participants. On average, the application received a score of 2.5.

Recommendation

Week 8

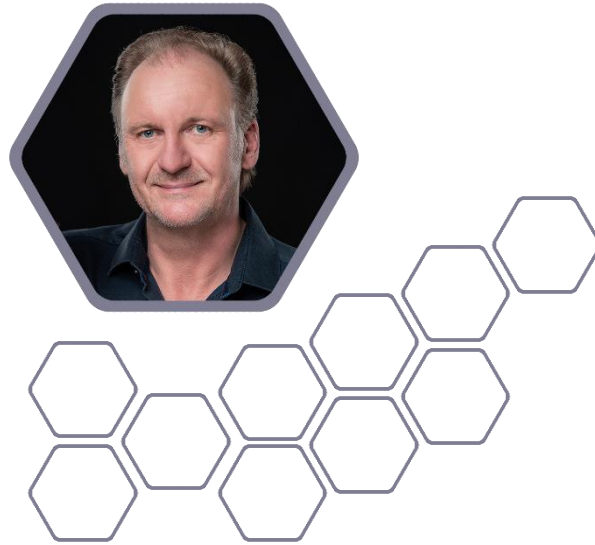
Would you recommend the CiQuit application to support cigarette reduction?



Note:

Most of all participants would recommend the CiQuit application to others.

Thank you very much



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What users say

Statements from the pilot study

*"**Very good thing**, thanks to the control I was able to reduce my cigarette consumption from 18-20 to an average of 13 after just 8 weeks."*

Rainer W.

*"**So I'm very enthusiastic**, I arrived on day 30 and I can only say one thing: simply great."*

Astrid P.

*"**The box made me realize** how often I had reached for a cigarette without thinking. Now, before every cigarette, I think about whether I really want it and how many I have left to achieve my own daily goal."*

Constanze K.

*"**It's simple to use**. The box remembers your smoking behaviour pretty quickly and I have to say that I smile every time the access time is increased. Habit becomes mindfulness!"*

Stefan F.

*"**I no longer light up a cigarette** without thinking or reflecting. I can easily do without one or two. It makes you proud and, in retrospect, happy. I believe it is possible to become a real non-smoker. The brain adjusts to it. Great invention!"*

Nils O.