



Cooperations with Health Insurance Funds



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Tabakkonsum

ist weltweit die größte
vermeidbare Ursache
für frühzeitige
Sterblichkeit.



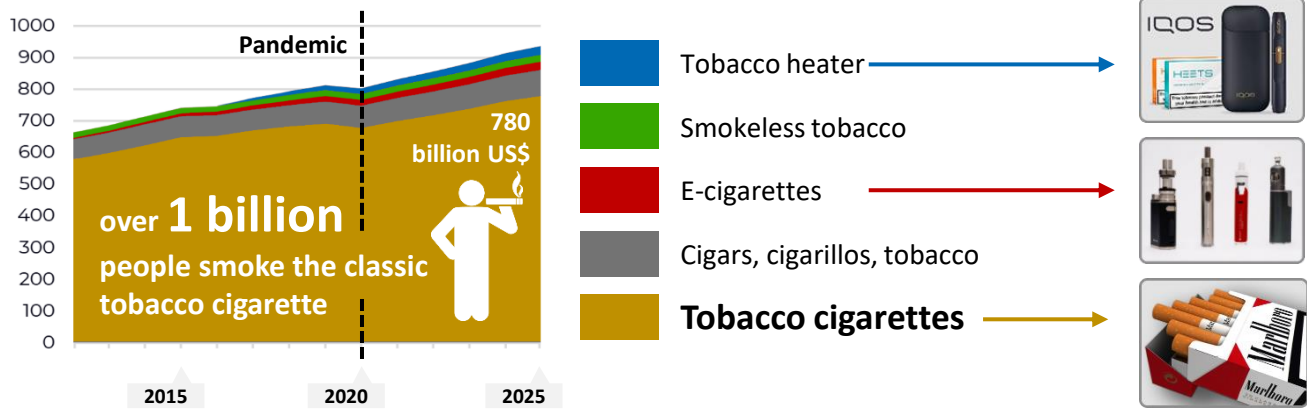
Further PDF documents

- **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/>

World Health
Organization

Worldwide
1.3 billion tobacco consumers

Global sales of tobacco products in US\$ billion, forecast to 2025¹



Factsheet:

Annual harm caused by the production and consumption of tobacco

Health

8 million lives and serious tobacco-related diseases

Economic costs

Around US\$ 1,4 trillion worldwide²

Environment

- 600 million trees
- 200,000 hectares of land
- 22 billion tons of water
- 84 million tons of climate-damaging CO₂³

Examples
Smokers in different countries

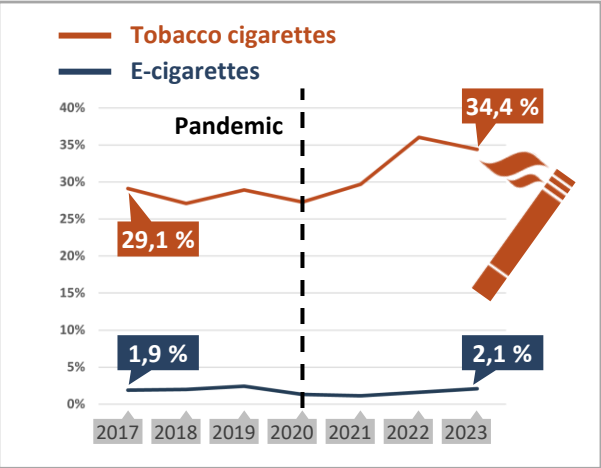
	Germany	around 25,000,000	
	Europe	around 115,000,000	
	USA	around 45,000,000	
	China	around 300,000,000	



Every year, an estimated **4.5 trillion** cigarette butts with more than 7,000 toxic chemicals end up in the environment.^{4,5,6}

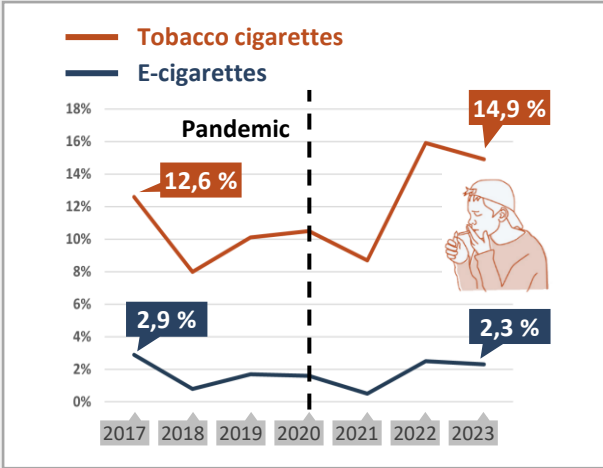
1) Source: <https://www.van-grunsteijn.com/sektoranalyse-tabak-resilienz-durch-anpassung>
2) Source: <https://www.paho.org/en/topics/tobacco-control>
3) Source: <https://www.paho.org/en/campaigns/world-no-tobacco-day-2022>
4) Source: <https://www.nabu.de/natur-und-landschaft/aktionen-und-projekte/meere-ohne-plastik/29901.html>
5) Source: <https://www.euwid-recycling.de/news/wirtschaft/jaehrlich-werden-45-billionen-zigarettenstummel-weggeworfen-170522/>
6) Source: https://www.euwid-recycling.de/fileadmin/data/euwid_recycling_und_entsorgung/news/images/Talking_Trash_EN.pdf

Since the pandemic, the number of people smoking tobacco cigarettes has skyrocketed.



DEBRA Deutsche Befragung zum Rauchverhalten				German survey on smoking behaviour	
Population 14 years +					
Measurement time	in millions	Prevalence	Smokers in millions		
11.05.2023	73,3	34,4%	25,2		
14.05.2022	73,3	36,0%	26,4		
03.06.2021	72,5	29,7%	21,5		
08.07.2020	72,5	27,3%	19,8		

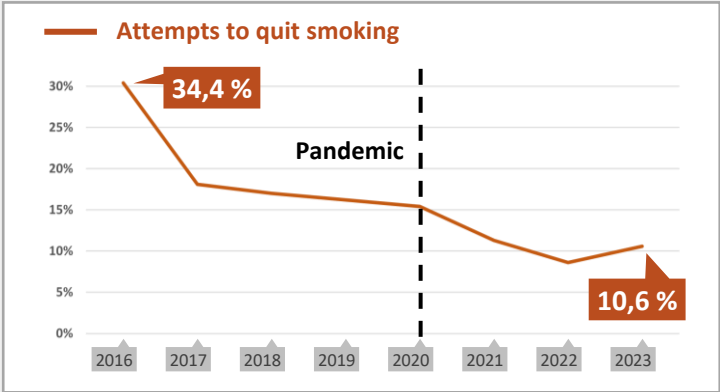
Unfortunately, the number of young smokers has risen just as sharply since the pandemic.



"It's a well-known phenomenon that people smoke more when the situation around them becomes less safe."¹

PD Dr. Tobias Effertz,
University of Hamburg

For years, the number of smokers who make at least one serious attempt to quit smoking has been declining.²



What the politicians say:

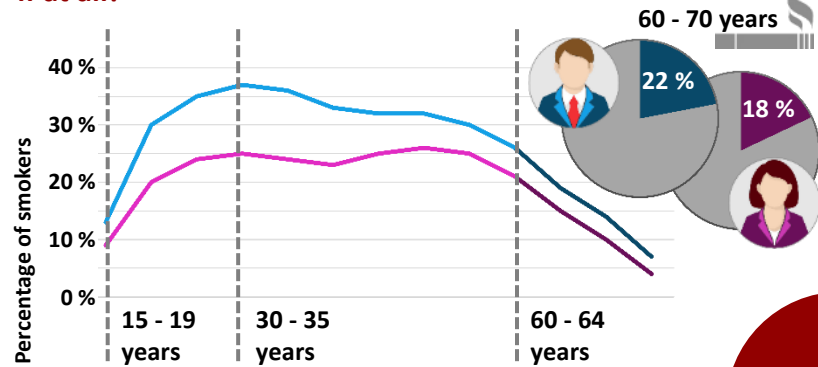
Burkhard Blienert
The Federal Government Commissioner
for Addiction and Drugs

"In the healthcare system, we finally must pull together in order to bring comprehensive help to quit smoking, onto the streets."³

1) Source: <https://www.n-tv.de/panorama/Immer-mehr-Deutsche-greifen-zum-Glimmstaengel-article23366473.html>
2) Source: DEBRA study German survey on smoking behavior, <https://www.debra-study.info/>
3) Source: <https://www.aerzteblatt.de/nachrichten/141011/Hilfe-beim-Rauchausstieg-Drogenbeauftragter-schlaegt-Anreize-fuer-Aerzte-vor>

Foreword | The Problem - Inability to Abstain 3/3

Permanent abstinence is achieved far too late,
if at all!



Current S3 guideline¹

"... Physical or psychological dependence makes quitting tobacco consumption more difficult and makes it a **protracted and often lifelong process characterized by relapses.**"

(S3 guideline: p. 10, para. 1, sentence 3)

"Between the ages of 20 and 50, a third of men and a quarter of women smoke. A significant decline in smoking can only be observed from the age of 60. But even here, the **proportion of smokers is still significant at 22% for men and 18% for women** (DHS 2020)."

(S3 guideline: p. 22, para. 3, sentence 2)

Inability to
abstain



"The **inability to abstain** is largely explained by an existing tobacco addiction, which is made up of pharmacological and psychological components. A decisive criterion of tobacco dependence is the reduction in control, which **makes it difficult or even impossible** for smokers to stop using tobacco by sheer willpower."²

Anil Batra
Head of the Department of Addiction Medicine and Addiction Research, UK Tübingen



Prof. Dr. Anil Batra

"The problem is that smokers too often quit far too late, on average after **five to ten attempts, which can sometimes last for decades.** By then, irreversible damage and smoking-related illnesses have long since been caused."³

Stephan Mühlig
Head of the Psychotherapeutic University Outpatient Clinic TU Chemnitz



Prof. Dr. Stephan Mühlig

"There is another misconception in the healthcare system: smoking is seen as a free choice. According to the motto: everyone has the right to harm themselves. This completely ignores the fact that many smokers are addicted. **And many people don't get the support they need.**"⁴

Ute Mons
Head of the Cancer Prevention Unit of the German Cancer Research Center (DKFZ)



Prof. Dr. Ute Mons

1) Source: https://register.awmf.org/assets/guidelines/076-006L_S3_Rauchen_-_Tabakabhaengigkeit-Screening-Diagnostik-Behandlung_2021-03.pdf

2) Source: https://www.dhs.de/fileadmin/user_upload/pdf/Broschueren/Suchtmedizinische_Reihe_Tabakabha%CC%88ngigkeit_BFREI.pdf

3) Source: <https://www.aerztezeitung.de/Medizin/Entwöhnung-kommt-oft-viel-zu-spaet-409870.html>

4) Source: <https://www.bmbf.de/bmbf/sharedocs/interviews/de/jede-dritte-krebserkrankung-ist-vermeidbar.html>

1. CiQuit quickly explained

Die schrittweise **Rekonditionierung**

der Tabakabhängigkeit 

erzielt motivierende, gesundheitsfördernde **Teilerfolge**

und maximiert den **Abstinenz-Erfolg**.



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: 3. Reaching smokers!

*see: 5. The status quo in tobacco cessation

1) Source: <https://docplayer.org/45668034-4-1-das-paradigma-zieloffener-suchtarbeit.html> | S. 198

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**.

Goal 1

Significant reduction in the consumption of cigarettes



without craving!

- Reduction > 50%
- At best 5 or less cigarettes a day

Goal 2

Improving the quality of life of smokers who (still) smoke



- Health benefits*
- Financial savings
- Mental well-being
- Improved sense of taste and smell
- Social acceptance

Goal 3

Motivation building and optimal preparation for quitting smoking



Ability to abstain



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."

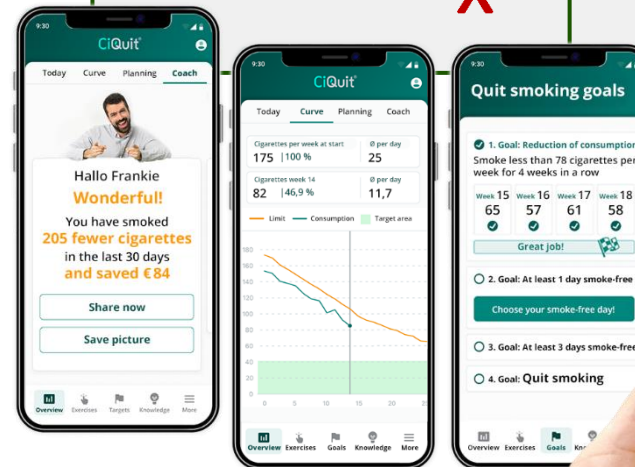
*Prof. Dr. Robert Olbrich,
Otto Selz Institute for Applied Psychology*

Reconditioning with CiQuit-Box and CiQuit-App



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



6 months (Basic setting)
Or adaptation to the progress of weaning.



CiQuit®
Reconditioning

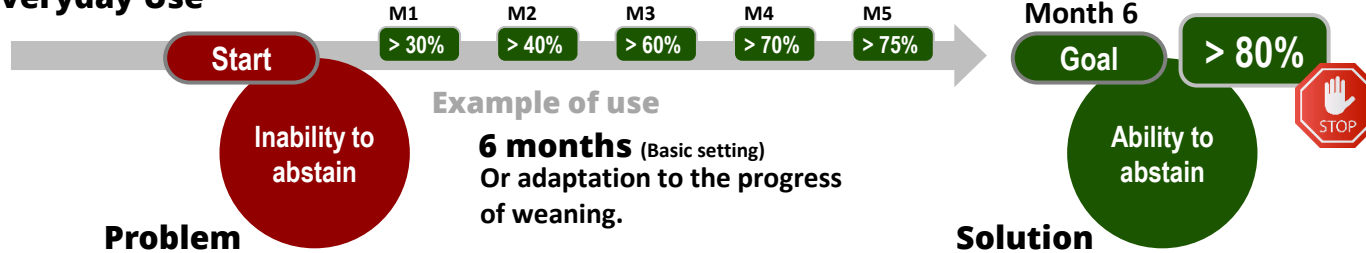


For a detailed explanation see:
www.luna-medical.com/en/scientific

The product and the path to abstinence

Unlearn smoking - relearn non-smoking!

- Digital
- Suitable for Everyday Use
- Step by Step



CiQuit-Box = Reconditioning

- The box accompanies 24/7 and enables **unlearning smoking** at the exact moment of craving!

CiQuit-App = Relearning Smoke-Free

- The app - Permanent **maintenance of motivation** and AI-supported roadmap to abstinence!

Behaviour control

Smoked today		2
Just available		3
Available later		8

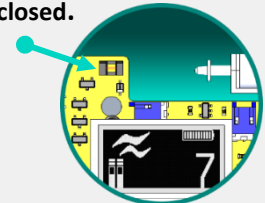
- 1 **Behaviour control**
via the display directly on the cigarette pack.

- 2 **Access delay**
via therapy-controlled locking directly on the cigarette pack.

- 3 **Hierarchical reduction**
AI-generated therapy adjustments are transmitted from the app to the box.

- 4 **Data measurement**

All necessary data are measured via a **light barrier** when the lid is opened and closed.

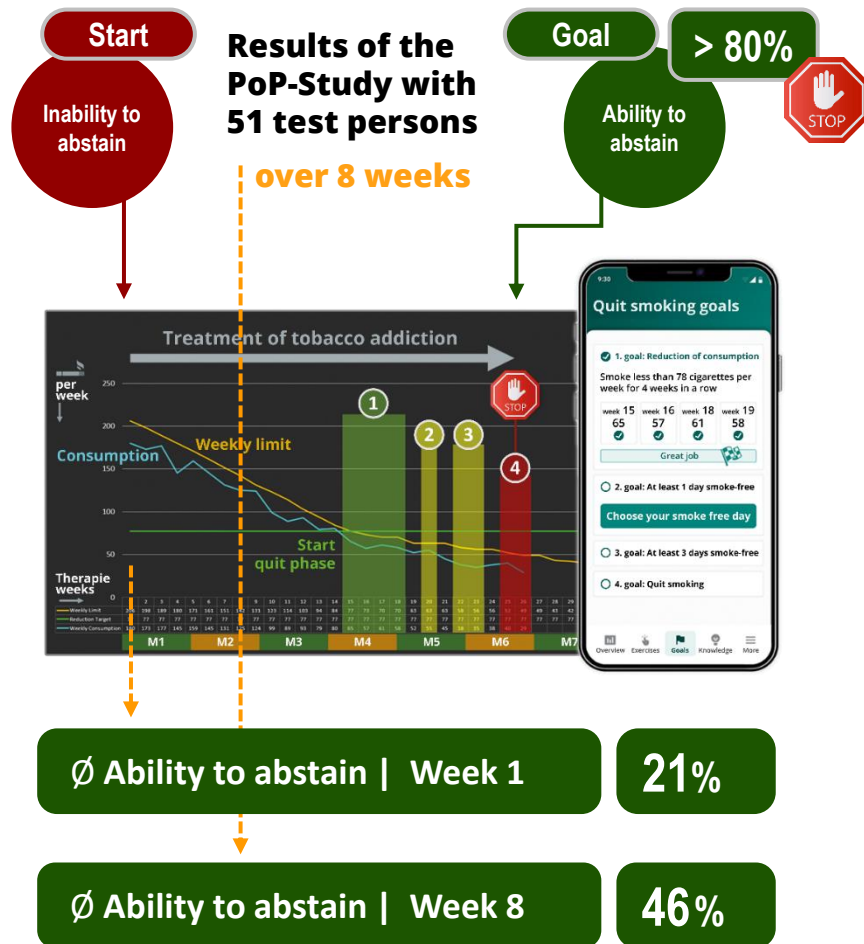


- 5 **Suitable for everyday use**

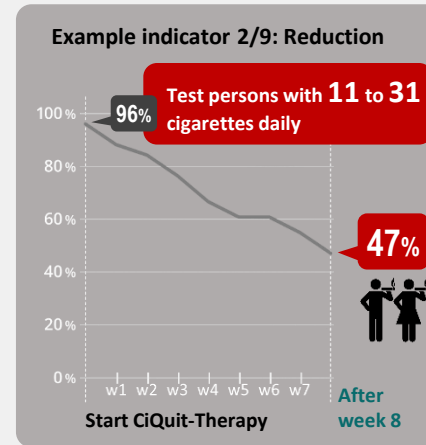
- No smoker would enter data into an app or keep a tally for every cigarette over an extended period of time.
- Should the box be forgotten, smoked cigarettes can alternatively be recorded in the app.

Proof-of-Principle Study (PoP-Study)

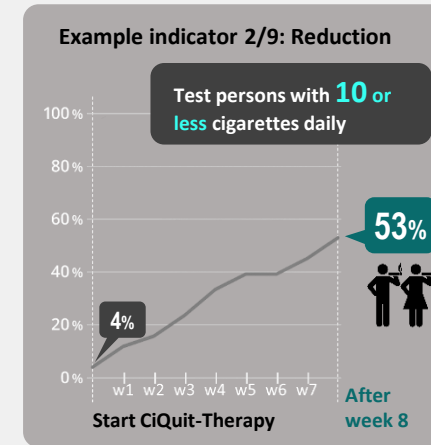
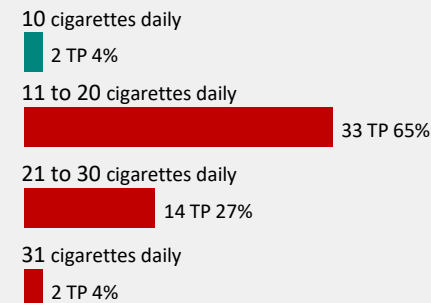
The successful study



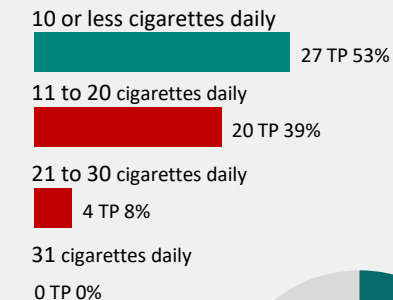
Significant improvements were observed in all 9 indicators of ability to abstain after just 8 weeks!



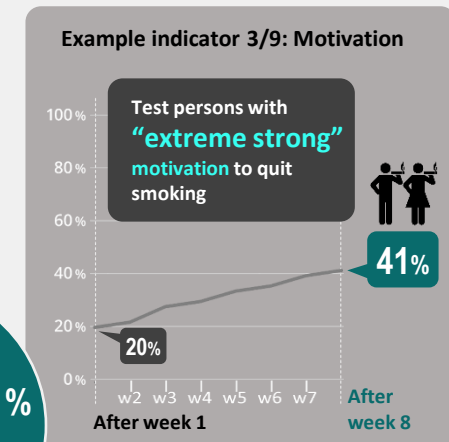
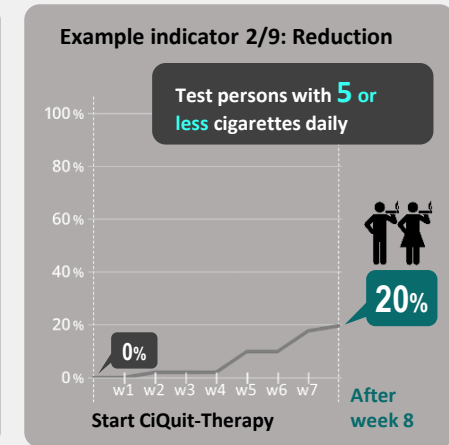
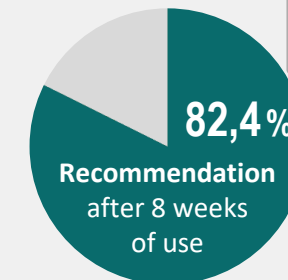
51 test persons (TP) Start



51 test persons (TP) Week 8



Proof-of-Principle Study
All results at
www.luna-medical.com/en/pop-study/



Primary problem and solution

From **reconditioning** to abstinence!



CiQuit
Reconditioning



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

> Worth knowing
9. Status quo ...

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

Large uncovered need

Smoke "less" first! = An easy way to start changing your behaviour

That's what science says!

"Glasgow et al. estimate that an additional 22% - 39% of smokers could be reached by a reduction offer."

This includes smokers who are willing to change their smoking behaviour but do not feel confident (initially) about quitting immediately, as well as smokers who currently do not wish to attempt quitting.¹



Competitors focus on switching to substitute products or quitting smoking immediately



Enormous healthcare gap

- Uncovered need
- No need
- Covered need

Covered need =  +  + 

Offers designed to help replace tobacco cigarettes



Tobacco heater



Key-companies: Philip Morris International, British American Tobacco, Japan Tobacco, Imperial Brands, Altria, China tobacco, Korea Tobacco & Ginseng Corporation, American electronic cigarette company, VMR Products

Global sales | Forecast 2030

US\$ 98,7 billion³



E-cigarettes



Key-companies: Altria Group, British American Tobacco, Imperial Brands, International Vapor Group, Japan Tobacco, International, NicQuid, JUUL Labs, Philip Morris International Inc, R.J. Reynolds Vapor Company, Shenzhen IVPS Technology Co., Ltd.,

Global sales | Forecast 2030

US\$ 63,4 billion⁴



Offers designed to support the **desirable** complete smoking cessation.



e.g.: Nicotine Replacement Therapy



Global sales | Forecast 2030

US\$ 3,9 billion⁵

1) Source: Quelle: https://edoc.ub.uni-muenchen.de/22126/1/Kiss_Alexa.pdf

2) Source: <https://www.van-grunsteyn.com/sektoranalyse-tabak-resilienz-durch-anpassung>

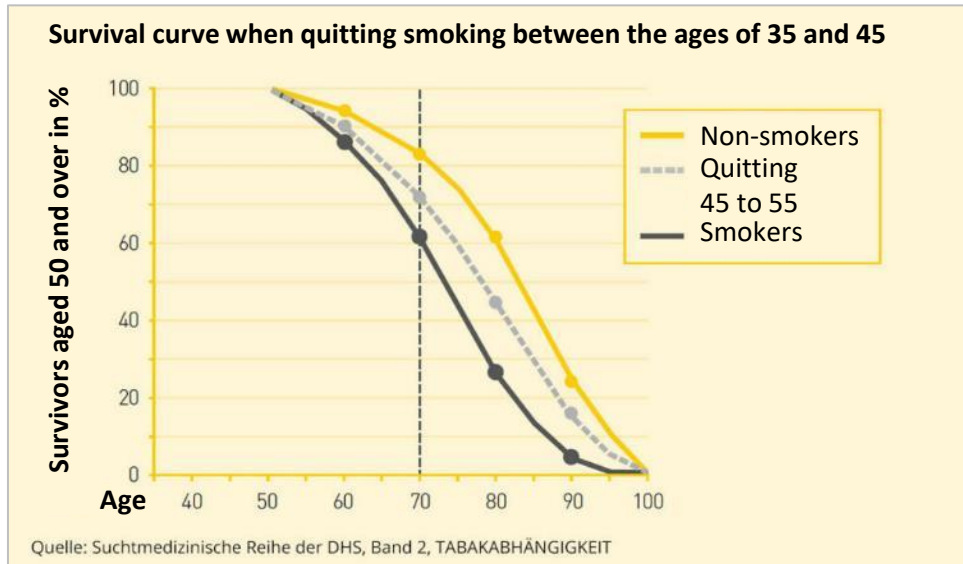
3) Source: <https://www.verifiedmarketreports.com/product/heated-tobacco-products-https-market-size-and-forecast/>
4) Source: <https://www.verifiedmarketreports.com/product/e-cigarette-and-vaping-market/>
5) Source: <https://www.researchandmarkets.com/reports/4968933/global-smoking-cessation-and-nicotine-de-addiction>

2. Advantages for health insurance funds



Improving the health of smokers

- Improving the quality of life
- Avoidance of tobacco-related diseases
- Avoidance of premature mortality



Quitting smoking between the ages of 45 and 55 is still associated with regaining 4.5 years of life.¹

Quit smoking ...

before the
age of 35

between
the ages of
35 and 45

between
the ages of
45 and 55

Statistical regaining of years of life

Similar
Non-smoker

8 years

4,5 years

"It's never too late to quit!"

says pulmonary specialist Robert Loddenkemper.

Measurements of exhalation force have shown that abstinence, even at the age of 65, can still delay death and disability by about five years.³

From a medical perspective, an early cessation is the best alternative!

Current S3 guideline²

Smokers live on average **10 years less** than non-smokers (Doll et al. 2004).

Increased mortality is also associated with increased morbidity, meaning smokers experience **fewer healthy years of life than non-smokers**, leading to a reduction in quality of life and participation.

(S3 guideline: p. 26, para. 2, sentence 2ff)

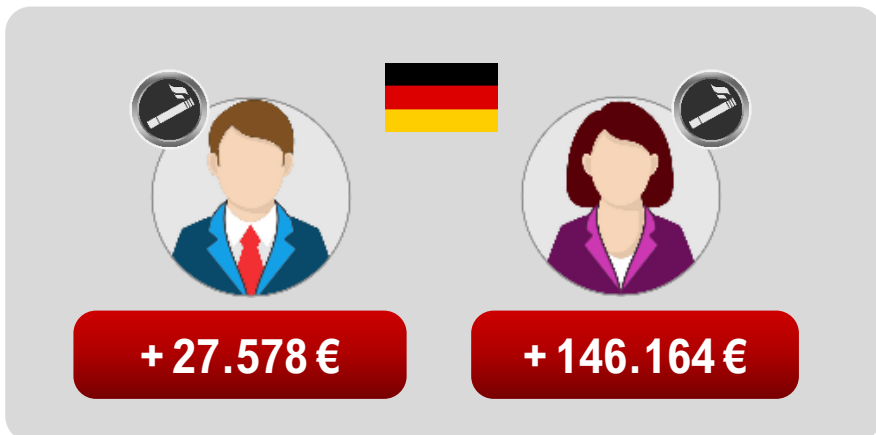
1) Source: Anil Batra, Peter Lindinger (2013) TABAKABHÄNGIGKEIT suchtmedizinische Reihe der DHS Band 2 |

https://www.dhs.de/fileadmin/user_upload/pdf/Broschueren/Suchtmedizinische_Reihe_Tabakabha%CC%88ngigkeit_BFREI.pdf

2) Source: https://register.awmf.org/assets/guidelines/076-006L_S3_Rauchen-_Tabakabhaengigkeit-Screening-Diagnostik-Behandlung_2021-03.pdf

3) Source: <https://www.spiegel.de/gesundheit/diagnose/rauchen-aufhoeren-im-alter-abstinez-lohnt-sich-immer-a-1286032.html>

Enormous cost savings in the healthcare sector



Current S3 guideline¹

"In the statutory health insurance system, the burdens become clearly evident: here, a smoker incurs additional costs compared to a non-smoker amounting to 27,578 euros, and female smokers, due to lower contributions, even 146,164 euros (Effertz 2015)."

(S3 Guideline: p. 25, para. 5)

"Given the immense costs of treating tobacco-related diseases, the cost-effectiveness of such measures, which are located in the outpatient health care sector, has been sufficiently proven."

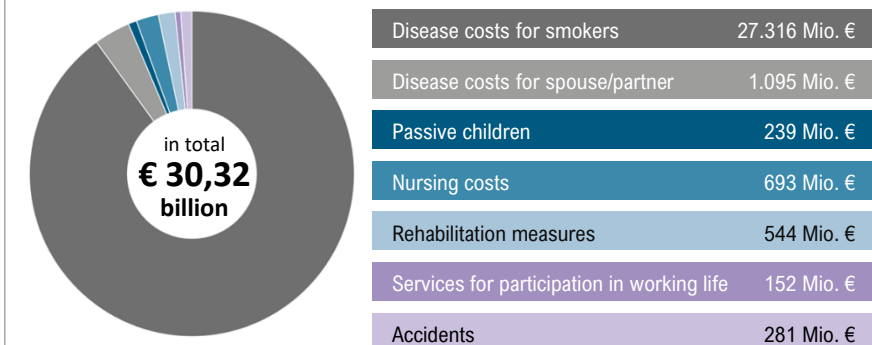
(S3 Guideline: p. 203, 4.9.8.1 Financing of tobacco cessation, sentence 4)

Thus, in Germany, **14.6% of the total expenditures in the health sector are caused by tobacco smoking.**

In total, the direct and indirect costs of smoking in Germany amount to **around 97 billion euros per year.**

Additionally, intangible costs, such as limitations on quality of life or the suffering and pain of those affected, are estimated at around 99 billion euros per year.²

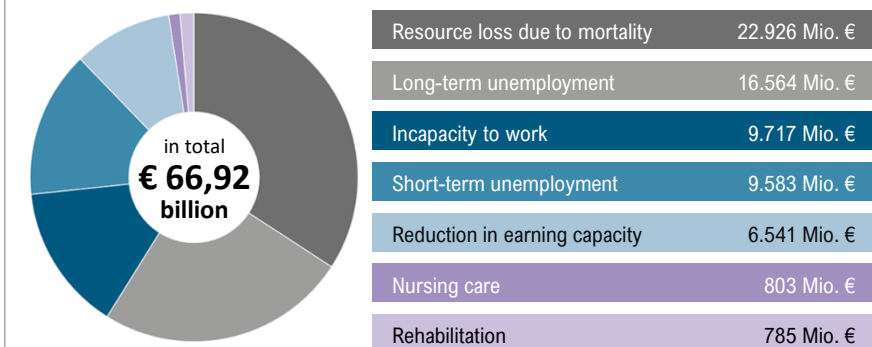
Direct costs of smoking in € million



Cost calculations: Effertz, the cost of smoking in 2018

Source: Federal Government Drug and Addiction Report 2019, BMG-D-11033

Indirect costs of smoking in € million



Cost calculations: Effertz, the cost of smoking in 2018

Source: Federal Government Drug and Addiction Report 2019, BMG-D-11033

Reach smokers!

Non-smoking courses are very rarely utilized!¹

 Spitzenverband  AOK  DAK Gesundheit  BARMER Deutschlands größte Krankenkasse  TK Techniker  IKK classic  KKH etc.		Benefits from statutory health insurance 					
		Individual behavioural prevention					
		2017	2018	2019	2020	2021	2022
Total course participation		1.675.008	1.685.490	1.805.889	1.157.305	796.595	1.294.193
Example field of action: Movement		1.159.826	1.155.187	1.223.676	732.653	466.144	769.853
Share in %		69,24%	68,54%	67,76%	63,31%	58,52%	59,49%
Example field of action: Stress management		438.854	462.829	514.285	363.332	275.593	452.486
Share in %		26,20%	27,46%	28,48%	31,39%	34,60%	34,96%
Example field of action: Addictive drugs		11.647	10.675	8.552	5.362	4.297	6.351
Share in %		0,70%	0,63%	0,47%	0,46%	0,54%	0,49%
Promotion of non-smoking		10.630	9.360	7.609	5.043	3.746	5.989
Share in %		0,63%	0,56%	0,42%	0,44%	0,47%	0,46%

Participants in non-smoking courses of all statutory health insurance funds in Germany (2019 - before the pandemic)



Why does
CiQuit
reach
smokers?



1) Source:

https://gkv-spitzenverband.de/krankenversicherung/praevention_selbsthilfe_beratung/praevention_und_bgf/praeventionsbericht/praeventionsbericht.jsp

3. Reach smokers!



Guiding principle

Please be understanding of smokers!

"Nicotine has a higher addictive potential than cocaine and heroin."

Dr. Michael Heidler,
Psychologist and head of institutes for tobacco cessation

The widespread belief:

**If someone doesn't want to quit smoking,
there's nothing you can do!** = **Wrong !!!**

"There is another misconception in the healthcare system: smoking is seen as a free choice. According to the motto: everyone has the right to harm themselves. This completely ignores the fact that many smokers are addicted. **And many people don't get the support they need.**" ¹

Ute Mons
Head of the Cancer Prevention Unit of the German Cancer Research Center (DKFZ)



The power of tobacco addiction

- Around **40%** of patients who have had their larynx removed try to continue smoking soon afterwards.
- Around **50%** of lung cancer patients who have undergone surgery resume smoking after the operation.²

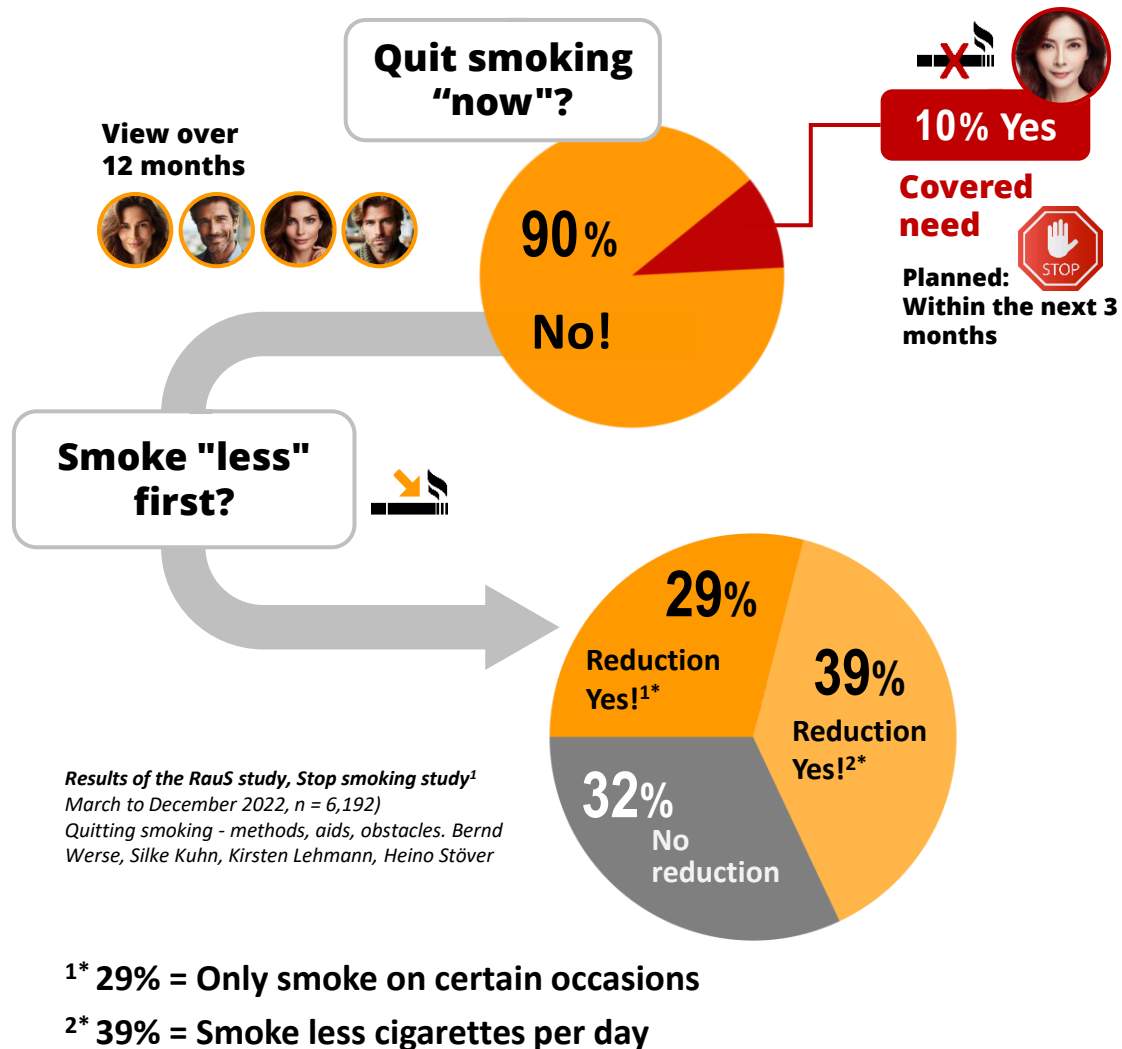
Correct is ...

- "Through a new, effective, and intensive support program, a lot can be achieved even with those who are seemingly 'unmotivated'.
- The primary goal of a therapeutic intervention is to increase the willingness to quit.
- **Smoking can be actively unlearned, and non-smoking can be newly learned.**"³

Prof. Dr. Anil Batra
Head of the Department of Addiction Medicine and
Addiction Research UK Tübingen

CiQuit and the enormous healthcare gap

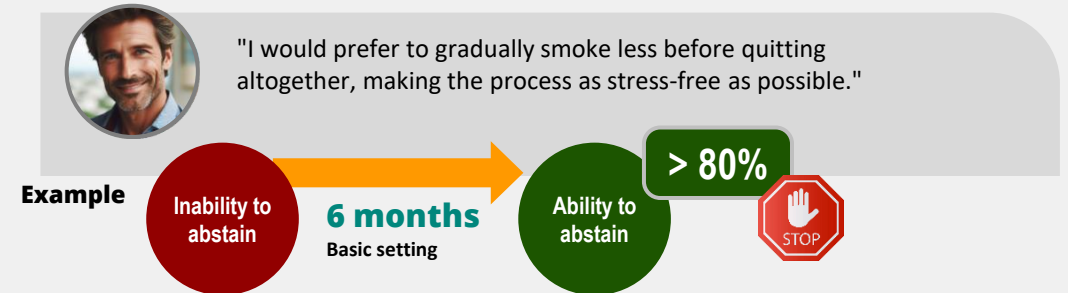
Uncovered need



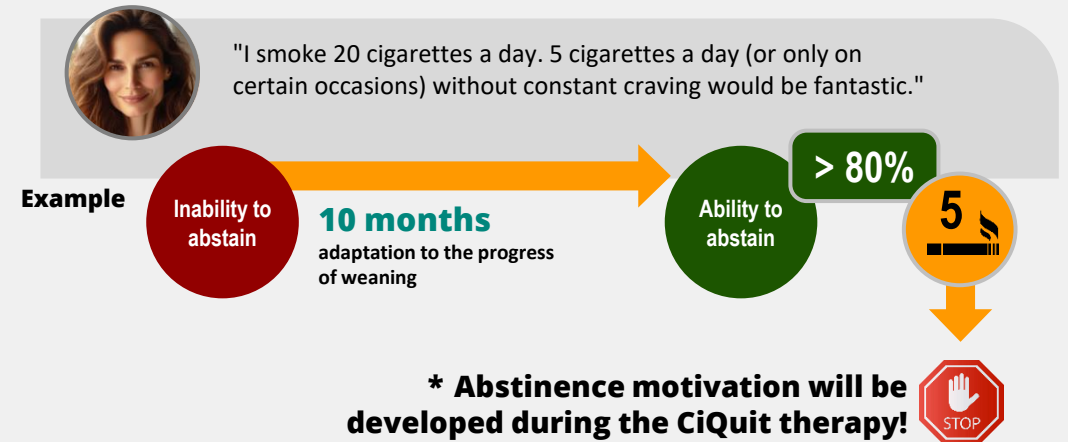
CiQuit®

... for the unfulfilled desire

1. The gentle introduction to smoking cessation



2. The permanent reduction of consumption*



CiQuit - Rubicon model: The quick decision to use

This is what the medical profession says!¹

Ineffectiveness

"Patients are usually only slightly motivated or not motivated at all to quit smoking."

Too time-consuming

"Initiating tobacco cessation is cumbersome and doomed to fail in most cases."

Quit smoking "now"!

Fear of losing something
"precious"!

- **Long** decision-making process
- **High** persuasion effort

- Fear of loss
- Fear of failure
- Failed attempts etc

The Rubicon **cannot**
be crossed



No, not now!

Rubicon model²

Choosing (pre-decisional phase):

The thought of quitting smoking completely can be overwhelming and daunting. In contrast, the goal of smoking less initially appears less threatening and more achievable.

Setting smaller goals, such as step by step reducing the daily cigarettes, helps reduce the feeling of being overwhelmed.

CiQuit - Smoke "less" first!

No fear of losing something
"precious"!

- **Fast** decision-making process
- **Low** persuasion effort

- No fear of loss
- No fear of failure
- No additional effort

The Rubicon can be
crossed **immediately**



Yes, I will!

Motivational psychology

Rubicon model

- It is important that wishes are transformed into concrete goals.
- This is known as crossing the Rubicon.

A clear goal ends choosing and sets the organism to "GO!"

- **Choosing**
Reduce your smoking?
Simple decision
= Yes, I will!
- **Planning**
The CiQuit therapy takes over!
- **Acting**
The CiQuit therapy will be realised!
- **Evaluating**
Subgoals successfully realised?
Maintaining motivation, as the partial successes adapt to the patient's progress.

Visibility in the target group

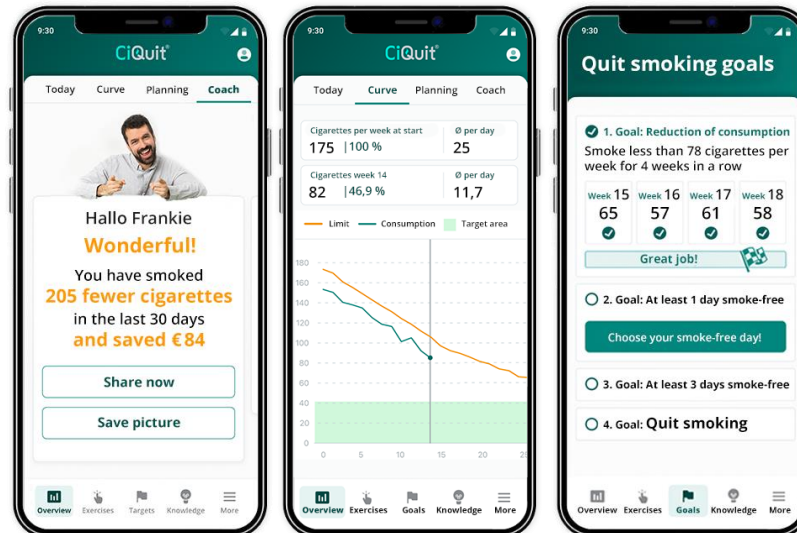
Experience shows that every CiQuit user is immediately approached by other smokers about the **CiQuit-Box**.

Other smokers are asking:

- **What is that?**
- **Where can I get this?**

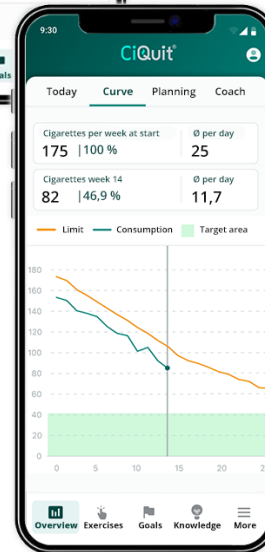
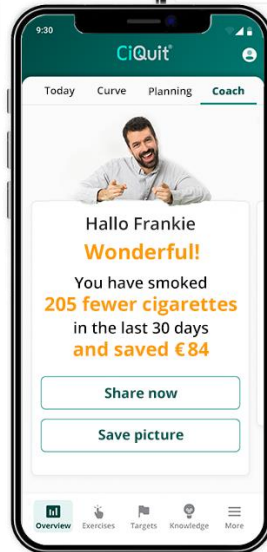
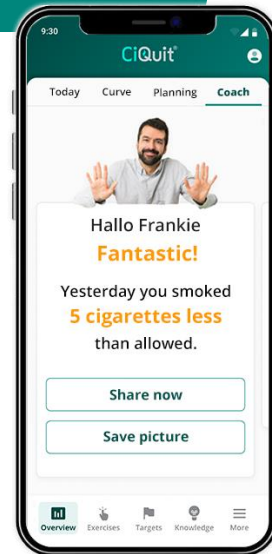


The CiQuit benefit can be communicated very easily via the **CiQuit-App**!



Why is the CiQuit-Box not bypassed?

If a diet reduces weight by 1 kilo every week and no hunger attacks occur, why should you deviate from the diet plan and eat on the side?



Keyword

Second cigarette pack



CiQuit

- generates daily and weekly motivating partial successes **without cravings.**
- adjusts in case of overwhelm and **prevents demotivating cravings.**
- weans the body and mind step by step, **prioritizing daily and weekly success over speed.**

If the box is ever forgotten, smoked cigarettes can alternatively be entered into the CiQuit-App.

4. Cooperation with health insurance funds



Cooperation before possible DiGA listing*

or countries without DiGA



*e.g. Germany 

§ 20 SGB V Primary Prevention and Health Promotion

(3) In carrying out the tasks according to paragraph 2 sentence 1, the National Association of Statutory Health Insurance Funds shall also consider the following health objectives in the area of health promotion and prevention:

3.Reduce tobacco consumption

Health Insurance Funds

insured persons

- E-mail
- Internet info portal



1. Smokers buy CiQuit

2. Smokers buy CiQuit with a subsidy from the health insurance funds

Cooperation after possible DiGA listing

or countries with cost coverage



Prescription e.g. via:

- Family doctor
- Tele doctor
- Company doctor



Health Insurance Funds

insured persons

- E-mail
- Internet info portal



Smokers receive CiQuit free of charge through their health insurance funds



Advantage health insurance funds



+ 27.578 €

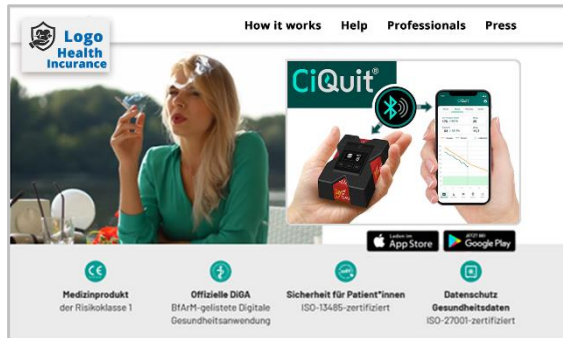


+ 146.164 €

Internet info portal

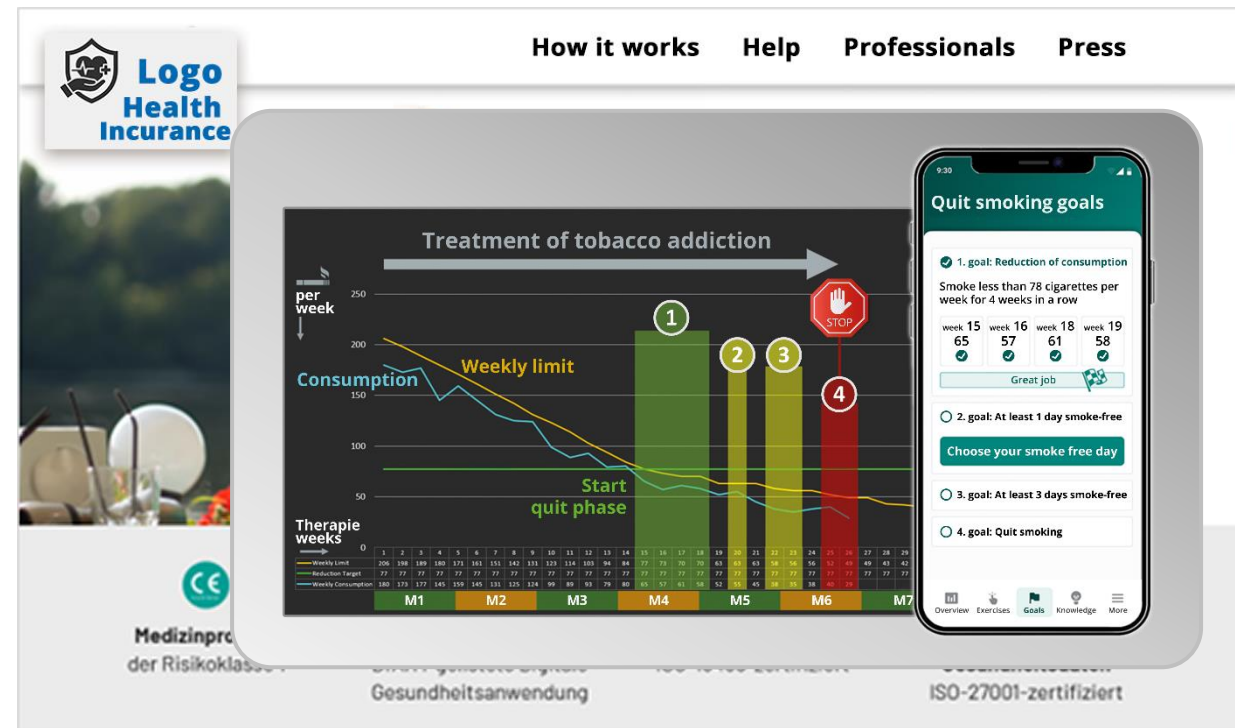
Step 1: E-mail

E-mail to insured persons with a link to an Internet information portal of



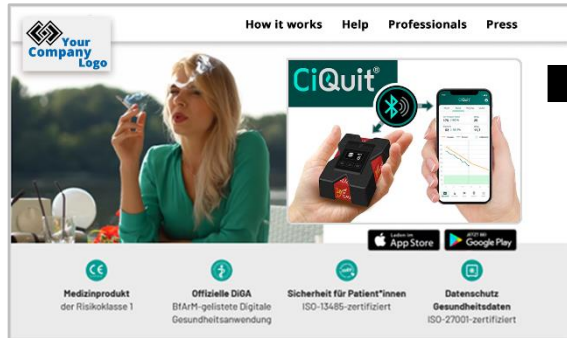
Step 2: Internet info portal

- Informationen
- Calculation of the individual weaning curve



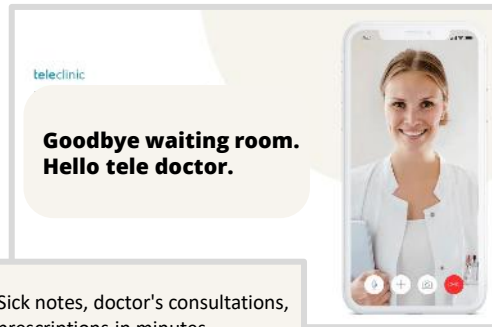
Internet info portal

Step 3: Different paths to CiQuit - directly from the internet information portal

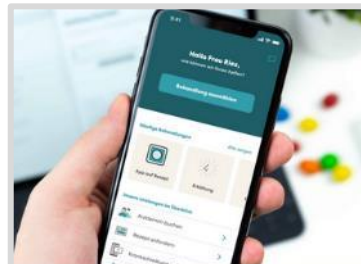


With prescription

Setup video call to Tele-Doktor

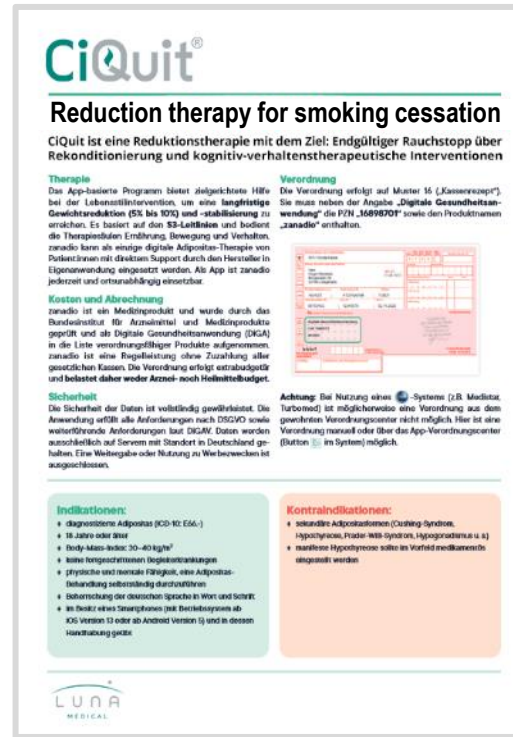


Sick notes, doctor's consultations, prescriptions in minutes.



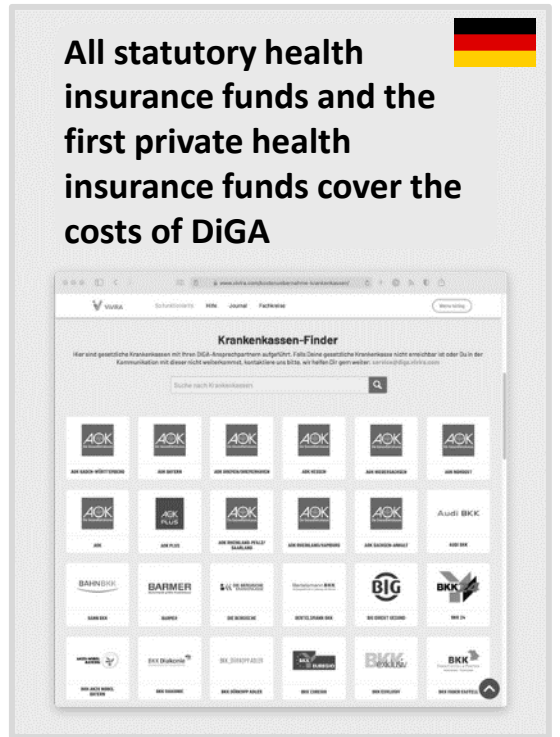
App on prescription.

Printout
1-pager for family doctor



Without prescription

Link for direct enquiry to health insurance funds



Prescription e.g. via:

- Family doctor
- Tele doctor
- Company doctor

5. The status quo in tobacco cessation

Quit smoking “now”! —X🚬

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!**



Thoughts and attitudes of the smoking workforce

Tobacco-dependent employees are often characterised by the following thoughts and attitudes:

If I quit,

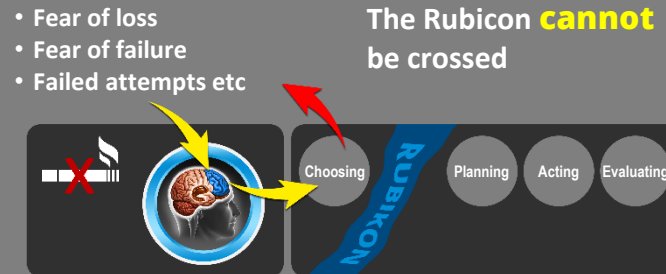
- I will just be a nervous wreck.
- I will be aggressive and unpalatable.
- I probably won't make it anyway and will feel like a failure.
- my work will suffer.
- my suffering will be great and long-lasting.
- I will gain weight.
- at best, I will become a lust-hostile, uncomfortable, boring and militant non-smoker.



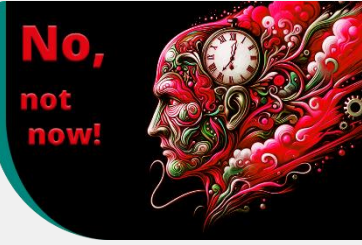
Quit smoking "now"!

Fear of losing something
"precious"!

- **Long** decision-making process
- **High** persuasion effort



No, not now!



Non-smoking courses vs. CiQuit reduction therapy



Non-smoking courses

Example:



Primary reasons why non-smoking courses are so rarely used:

- **Lack of motivation for quit smoking "now"**
- **Fear of failure:**
The fear of failing and the associated loss of face at friends and family.
- **Lack of privacy:**
Participating in courses requires a certain openness about personal habits, which people are reluctant to disclose.
- **Overestimation of self:**
The difficulties in overcoming nicotine addiction are underestimated. This leads to the belief that one can manage without professional support, even when this is not the case in reality.

CiQuit-Reduction therapy



Primary reasons why CiQuit will be used much more frequently:

- **No immediate need to quit smoking**
- **Motivating partial successes:**
Initially smoking a little less is seen as an achievable goal for every smoker.
- **High level of privacy:**
Participation does not require openness about personal habits. Even patient-specific longer therapy durations do not need to be communicated.
- **Persuasive reasoning:**
Quitting smoking is a learnable skill, not fate. Good preparation - "Restoring the ability to abstain" - creates optimal chances of success. Just like any important exam or new type of sport, optimal preparation is key to success.

CiQuit - Smoke "less" first!

No fear of losing something "precious"!

- **Fast decision-making process**
- **Low persuasion effort**

• No fear of loss
• No fear of failure
• No additional effort

The Rubicon can be crossed **immediately**



Yes, I will!

Success rates in tobacco cessation

Non-smoking courses are very rarely utilized!¹

	Benefits from statutory health insurance					
	Individual behavioural prevention					
	2017	2018	2019	2020	2021	2022
Total course participation	1.675.008	1.685.490	1.805.889	1.157.305	796.595	1.294.193
Example field of action: Movement	1.159.826	1.155.187	1.223.676	732.653	466.144	769.853
Share in %	69,24%	68,54%	67,76%	63,31%	58,52%	59,49%
Example field of action: Stress management	438.854	462.829	514.285	363.332	275.593	452.486
Share in %	26,20%	27,46%	28,48%	31,39%	34,60%	34,96%
Example field of action: Addictive drugs	11.647	10.675	8.552	5.362	4.297	6.351
Share in %	0,70%	0,63%	0,47%	0,46%	0,54%	0,49%
Promotion of non-smoking	10.630	9.360	7.609	5.043	3.746	5.989
Share in %	0,63%	0,56%	0,42%	0,44%	0,47%	0,46%

1) Source:
https://gkv-spitzenverband.de/krankenversicherung/praevention_selbsthilfe_beratung/praevention_und_bgf/praeventionsbericht/praeventionsbericht.jsp

Participants in non-smoking courses of all statutory health insurance funds (2019 - before the pandemic)



≈ 35 %

Non-smoking courses

In clinical practice, professional tobacco cessation treatments report 12-month abstinence rates between 25% and 40%.¹⁰ Intensive interventions with multiple contacts before and after the quit date achieve higher abstinence rates.¹¹

Excursus

Success rates in tobacco cessation



Only own willpower

With a firm resolution to quit smoking for good and never to light up a cigarette again, the probability of abstinence one week after making the resolution is 25%, and six months later, it already falls below 5%.² Unassisted attempts to quit smoking succeed in only 3% to 5% of cases.³

≈ 5 %



Apps and Online programs

Mobile self-help programs, S3 guideline: This Risk Ratio (RR) means that on average, 5.6% in the control groups and 9.3% in the intervention groups have successfully quit smoking.⁴ NichtraucherHelden-App (DiGA), study result: The NichtraucherHelden-App doubles the abstinence rate.⁵

≈ 10 %



Nicotine Replacement Therapy

63 studies with 41,509 participants: 17% who combined a patch with another intervention were able to quit, compared with 14% who used a single form of Nicotine Replacement Therapy (NRT).⁶ 16%, die NET nutzten, rauchten nicht mehr. 11%, die ein Placebo verwendeten, rauchten nicht mehr.⁷

≈ 15 %



Medication e.g.: Champix, Zyban

25% who took varenicline (Champix) no longer smoked. 11% who took a placebo no longer smoked.⁸ 19% who took bupropion (Zyban) no longer smoked. 12% who took a placebo no longer smoked.⁹

≈ 25 %

2) Source: https://www.dhs.de/fileadmin/user_upload/pdf/Broschueren/Suchtmedizinische_Reihe_Tabakabha%CC%88ngigkeit_BFREI.pdf

3) Source: <https://www.aerzteblatt.de/pdf.asp?id=221166> | Trial and failure

4) Source: https://register.awmf.org/assets/guidelines/076-006I_S3_Rauchen_-_Tabakabhaengigkeit-Screening-Diagnostik-Behandlung_2021-03.pdf

5) Source: <https://drks.de/search/de/trial/DRKS00025933> | Basic results | Conclusions

6) Source: <https://www.cochrane.de/news/ein-neuer-cochrane-review-untersucht-die-wirksamkeit-von-unterschiedlichen>

7) Source: <https://www.stiftung-gesundheitswissen.de/wissen/rauchentwohnung/koennen-nikotinplaster-und-co-bei-der-rauchentwohnung-helfen>

8) Source: <https://www.stiftung-gesundheitswissen.de/wissen/rauchentwohnung/kann-vareniclin-bei-der-rauchentwohnung-helfen>

9) Source: <https://www.stiftung-gesundheitswissen.de/wissen/rauchentwohnung/kann-bupropion-bei-der-rauchentwohnung-helfen>

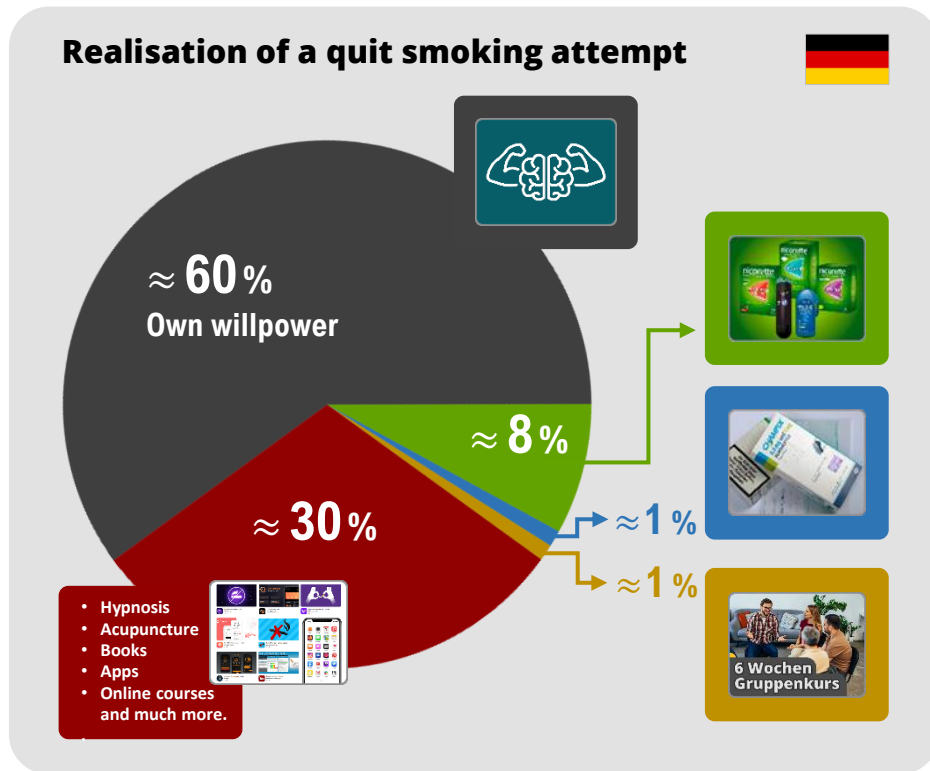
10) Source: https://register.awmf.org/assets/guidelines/076-006I_S3_Rauchen_-_Tabakabhaengigkeit-Screening-Diagnostik-Behandlung_2021-03.pdf

11) Source: https://www.dhs.de/fileadmin/user_upload/pdf/Broschueren/Suchtmedizinische_Reihe_Tabakabha%CC%88ngigkeit_BFREI.pdf

Relying only on willpower - The wrong strategy

Problem

Attempts to quit smoking on one's own willpower despite a very low success rate, as many smokers overestimate their ability to quit smoking without support. This overestimation leads to the avoidance of evidence-based assistance, in the hope of being successful through their own willpower. Evidence-based assistance, at least, increases the chances of success.



Own willpower



Unassisted attempts to quit smoking succeed in only 3% to 5% of cases.¹

With a firm resolution to quit smoking for good and never to light up a cigarette again, the probability of abstinence one week after making the resolution is 25%, and six months later, it already falls below 5%.²

Important! S3 guideline³

"Unlike many other health interventions, individuals seeking to quit smoking are typically not advised by a medical consultant on the most effective method based on scientific evidence. Instead, those affected often inform themselves in a loosely regulated market of tobacco cessation offerings."

Nicotine

Replacement Therapy



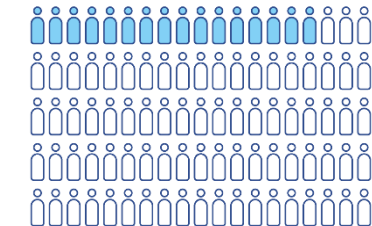
Success rate

≈ 15 %

63 studies with 41,509 participants: 17% who combined a patch with another intervention were able to quit, compared with 14% who used a single form of Nicotine Replacement Therapy (NRT).⁴

Do nicotine replacement products help to quit smoking? ⁵

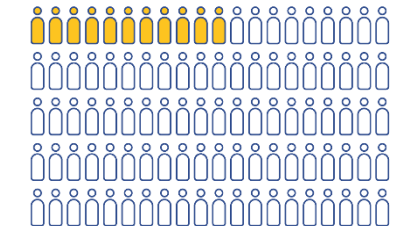
Nicotine replacement products



16 out of 100 people who used a nicotine replacement product no longer smoked.*
*(After 6 or 12 month)

Quelle: Hartmann-Boyce et al. (2018)

Placebo products



11 out of 100 people who used a placebo product no longer smoked.*

1) Source: <https://www.aerzteblatt.de/pdf.asp?id=221166> | Versuch und Scheitern

2) Source: https://www.dhs.de/fileadmin/user_upload/pdf/Broschueren/Suchtmedizinische_Reihe_Tabakabha%CC%88ngigkeit_BFREI.pdf

3) Source: https://register.awmf.org/assets/guidelines/076-006l_S3_Rauchen-_Tabakabhaengigkeit-Screening-Diagnostik-Behandlung_2021-03.pdf

4) Source: <https://www.cochrane.de/news/ein-neuer-cochrane-review-untersucht-die-wirksamkeit-von-unterschiedlichen>

5) Source: <https://www.stiftung-gesundheitswissen.de/wissen/rauchentwoehnung/koennen-nikotinplaster-und-co-bei-der-rauchentwoehnung-helfen>

Barriers to utilizing offers of help Effort, side effects, costs

CiQuit: No or only low barriers to utilisation

	High willingness to use						
	Low willingness to use						
Example Germany 							
Target group	Method of implementation	Effort during use	Side effects	Costs	Use of the method in %	Quit smoking attempts per year	Success rate

Covered need - quit smoking „now“! (Methods with high evidence)

10 %	 Own willpower	No	No	No	60 %	1.200.000	≈ 5 %	One goal: Quit smoking YES or NO
	 NRT Nicotine replacement therapy	No	Low	High ≈ 150 -300 €	8 %	160.000	≈ 15 %	
	 Medication e.g. Zyban, Champix	No	High	High ≈ 150 - 300 €	1 %	20.000	≈ 25 %	
	 Courses with presence	High	No	High ≈ 150 - 250 €	1 %	20.000	≈ 35 %	

Uncovered need - Smoke „less“ first!

60 %		No	No	Medium ¹	= high willingness to use
		No	No	No ²	

Several goals:

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

Goal: Inability to abstain > 80%



Current S3 guideline¹

“When planning interventions, it should be considered that with increasing intensity of an intervention, acceptance among the target group and thus their accessibility, as well as the proportion of regular completers, decreases.”

(S3 guideline: p. 97, para. 3, sentence 1)

Comparison of countries²

Use of Nicotine Replacement Therapy (NRT) during an attempt to quit smoking depending on the cost coverage by the healthcare system.




Germany

Cost coverage **NO**

8%

Using NRT during an attempt to quit smoking




England

Cost coverage **YES**

48%

Using NRT during an attempt to quit smoking

1) Costs may be subsidised by health insurance companies and/or employers

2) Cost coverage by health insurance companies as DiGA = digital health application according to MDR I

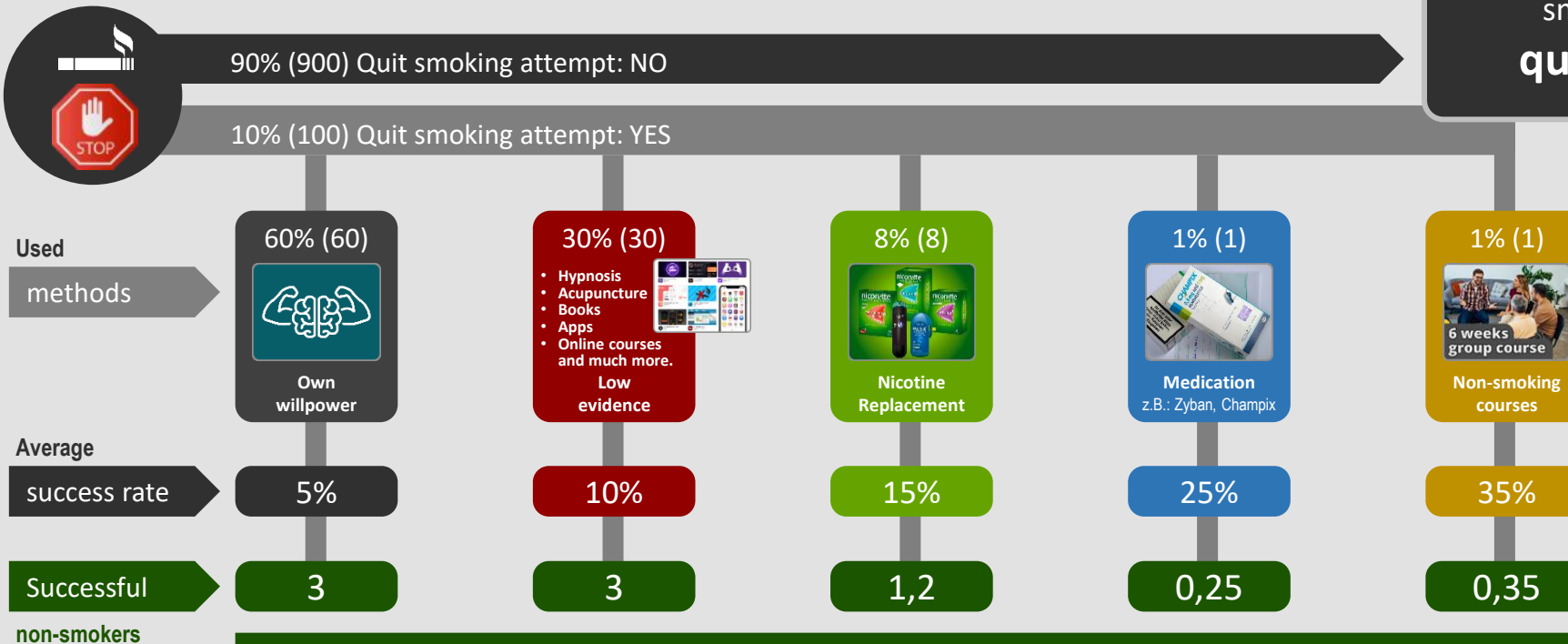
1) Source: https://register.awmf.org/assets/guidelines/076-006I_S3_Rauchen_-_Tabakabhaengigkeit-Screening-Diagnostik-Behandlung_2021-03.pdf
2) Source: <https://www.aerzteblatt.de/archiv/211741/Rauchstoppversuche-und-genutzte-Entwöhnungsmethoden>

High relapse rates despite many offers of help

Far too few smokers achieve the leap into permanent abstinence each year.

Extrapolation: ≈ Successful attempts to quit smoking
- over 1,000 tobacco-dependent smokers - per year

Only 8 out of 1,000
smokers are able to
quit every year!

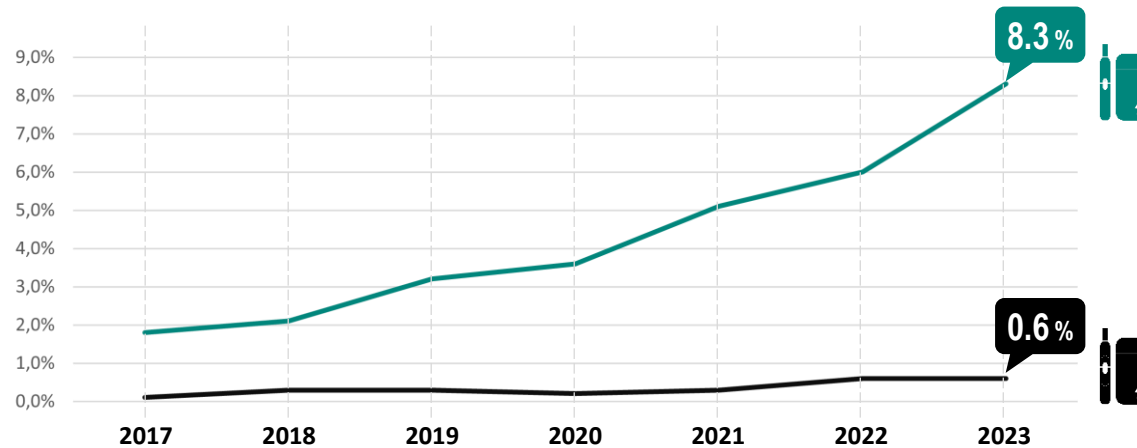


Relapse rate
92%
on average

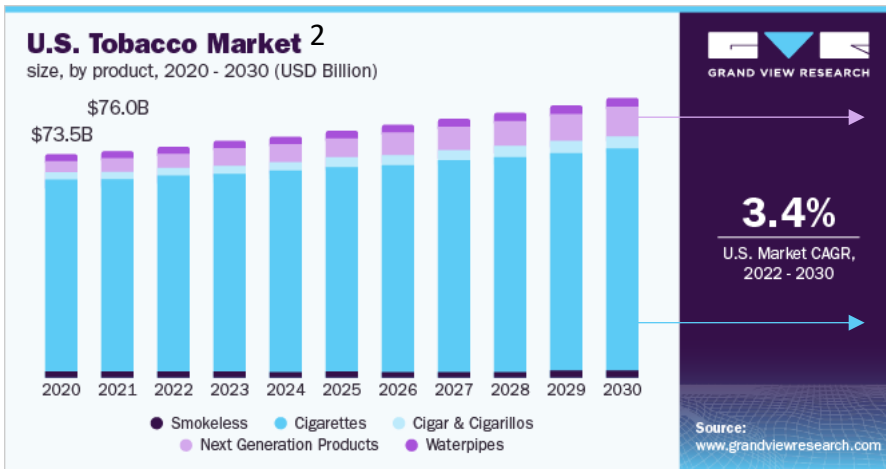
Tobacco heaters (IQOS & Co.) - Germany as an example

In 2023

- **8.3%** of those aged over 14 reported currently using **or having tried tobacco heaters**.
- **only 0.6%** of those aged over 14 reported actually using tobacco heaters.¹



DEBRA
Deutsche Befragung zum Rauchverhalten 
German survey on smoking behaviour



Tobacco heaters and E-cigarettes*



Traditional cigarettes



Many smokers return to traditional cigarettes after trying tobacco heaters or e-cigarettes for various reasons:

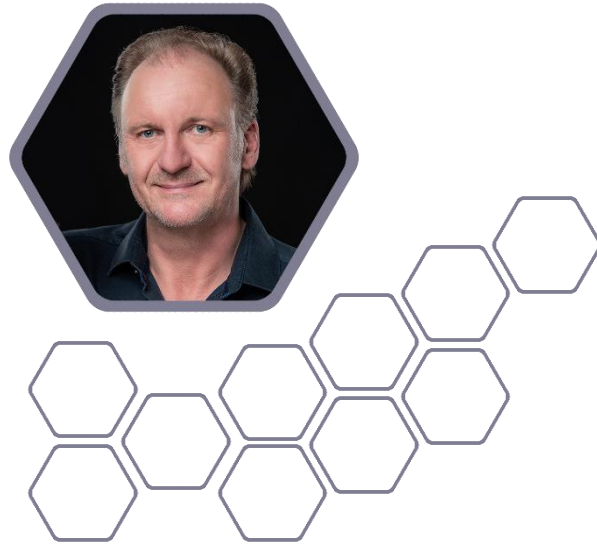
- 1. Insufficient Nicotine Hit and Satisfaction:** Alternative products often fail to replicate the familiar nicotine sensation and kick of conventional cigarettes.
- 2. Complexity and Maintenance:** The higher maintenance required for e-cigarettes and heaters compared to traditional cigarettes is seen as cumbersome.
- 3. Technical Issues:** Device failures such as battery outages or refill problems can cause frustration.
- 4. Social and Cultural Factors:** Social surroundings and traditional smoking habits can hinder the use of alternative products.
- 5. Regulatory Restrictions:** Stricter regulations for e-cigarettes and heaters, including flavour bans, can reduce their appeal.
- 6. Taste and Sensory Experience:** Many smokers prefer the taste and smoking experience of traditional cigarettes over the perceived artificial flavours of e-cigarettes.
- 7. Doubts about Cessation Effectiveness:** Uncertainties about the efficacy of these products as smoking cessation aids lead some smokers to revert to cigarettes.

*In some countries, the possession of tobacco heaters, e-cigarettes and liquids is strictly prohibited and can be punished with severe penalties. These include holiday destinations such as Brazil, Singapore and Thailand (as of September 2023). <https://www.iqos.com/de/de/news/services-support/reisen-mit-tabakerhitzern-travelguide.html>

1) Source: <https://www.debra-study.info/>

2) Source: <https://www.grandviewresearch.com/industry-analysis/us-tobacco-market>

Thank you very much



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Attachments



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.

Attachments

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CiQuit

Accompanies 24/7 and enables **unlearning smoking** at the exact moment of craving!

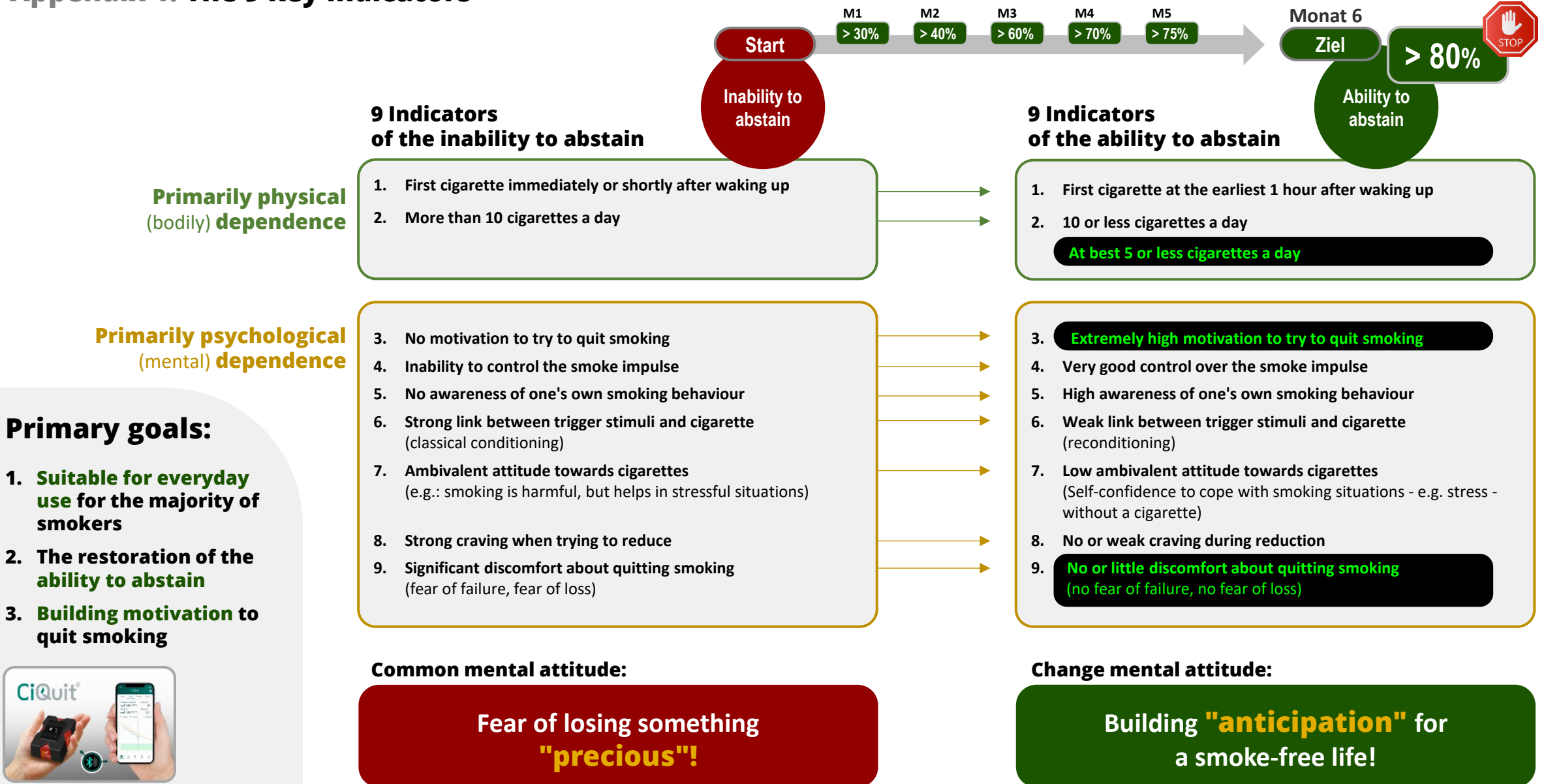
The scientific background

Detailed information see

<https://www.luna-medical.com/en/scientific/>



Appendix 1: The 9 key indicators

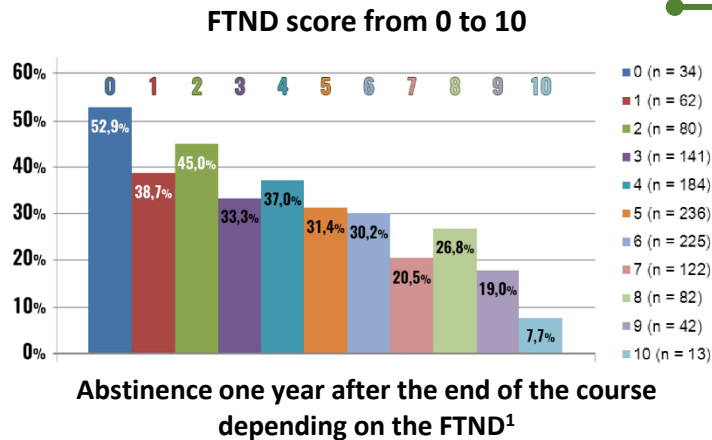


Appendix 2: CiQuit goals and the scientific derivation

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

Abstinenz-
Fähigkeit

9 CiQuit® goals



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).

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"

6 weeks
group course

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>

Appendix 3: The scientific background to CiQuit

A core principle from science

"Successful smoking cessation depends on how the learned habit of smoking can be permanently **"deleted!"** from the relevant brain area."

*Prof. Dr. Joseph McClernon,
Development of interventions against nicotine addiction*

Goal



Ability to
abstain



The core principle of CiQuit

CiQuit shifts the process of smoking from the "hot system" to the "cool system" and deletes the habit (addiction) of smoking from the relevant brain regions!

Learning and unlearning **"delete!"** is not possible in the "hot system"!



Learning and unlearning **"delete!"** can only be implemented in the "cool system"!



The **"hot system"** in the context of cigarette smoking:

The "hot system" is impulsive, operating automatically and subconsciously. In cigarette smoking, the "hot system" is activated by the anticipation (excitement) of immediate enjoyment and relaxation that nicotine provides. It responds to cravings as well as stress, boredom, and many other triggers that lead to reaching for a cigarette.

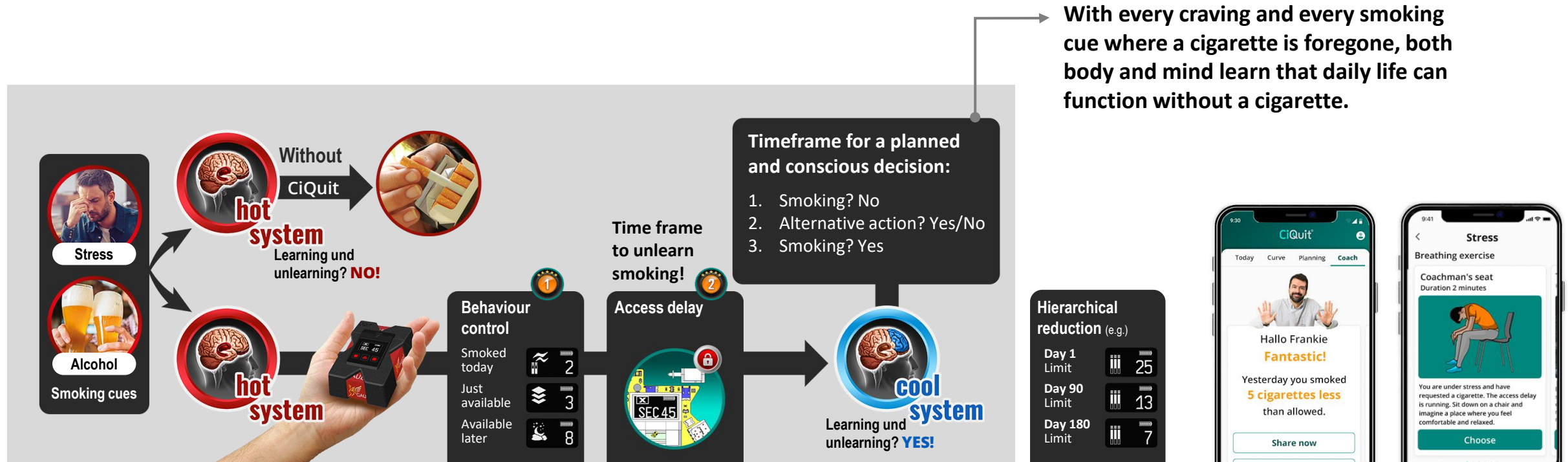
The **"cool system"** in the context of cigarette smoking:

The "cool system" is analytical and future-oriented. It considers long-term consequences and health risks associated with smoking.

- Through the CiQuit-Box, the **"cool system"** is activated every time you reach for a cigarette.
- This counters the smoking impulse, which is subconsciously initiated by the **"hot system"**.
- The process of reconditioning, which is only possible through the **"cool system"**, is now achievable without addiction pressure through the CiQuit-Box.



Appendix 4: Summary - The primary task of the CiQuit-Box



The CiQuit-Box

The box accompanies 24/7 and enables **unlearning smoking** at the exact moment of craving!

* The access delay increases slowly every day.

Examples:

Day 1
20 seconds

Day 39
1:17 minutes

Day 83
2:46 minutes

The body and mind adapt to the slowly increasing access delays and do not generate any agonising cravings during the access delays.

- The "hot system" drives us to satisfy needs that promise immediate gratification, without considering the long-term effects on us.
- In contrast, the "cool system" allows for a rational evaluation of action options and is based on the activation of brain regions for self-control, learning and unlearning.
- 1. **Effective behaviour control** requires the observation and documentation of problematic behaviours, with the observation itself leading to positive changes.
- The CiQuit Box prevents uncontrolled and subconscious access to cigarettes by keeping the pack locked, which does not mean denying access to cigarettes.
- 2. Instead, the **access delay** creates a window of time that allows the user to actively unlearn smoking in the relevant brain regions, the "cool system," at the very moment of craving.

Appendix 5: Summary - The primary task of the CiQuit-App



The CiQuit-App

Permanent maintenance of motivation and AI-supported roadmap to abstinence!

- **Success experiences** in professions, sports, or changing behaviors are crucial for maintaining motivation. Success generates positive emotions, which, through the release of dopamine in the reward center, maintain this motivation.
- **Both self-reinforcement and external reinforcement** (pride, praise, recognition) play a significant role in establishing a new reward system, as these reinforcers create positive emotions (success) and thus initiate the release of dopamine.
- The CiQuit app triggers these reinforcers, among other things, through the **visualization of partial successes and success messages**, further enabling the continuous evaluation of changes and thereby stabilizing the modification process.
- "If-Then" plans are an effective self-regulation strategy to transform good intentions into successful actions. The app offers specific action alternatives for individual smoking situations (promoting reconditioning).

As a result, the interplay between the box and the app realizes a core principle of behavior therapy:

"Smoking can be actively unlearned, and non-smoking can be newly learned."