

# Cooperations with Health Insurance Funds





# Contents

Fo	preword	3
1.	CiQuit quickly explained	6
2.	Advantages for health insurance funds	13
3.	Reach smokers!	17
4.	Cooperation with health insurance funds	23
5.	The status quo in tobacco cessation	

### **Attachments**

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Appendix 1: CiQuit and DiGA	38
Appendix 2: CiQuit and the DiGA directory	39
Appendix 3: The 9 key indicators	40
Appendix 4: CiQuit goals and the scientific derivation	41
Appendix 5: The scientific background to CiQuit	42
Appendix 6: Summary - The primary task of the CiQuit-Box	43
Appendix 7: Summary - The primary task of the CiQuit-App	44

# Tabakkonsum

ist weltweit die größte vermeidbare Ursache für frühzeitige Sterblichkeit.



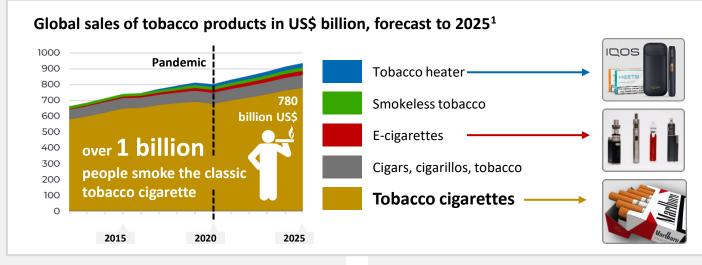
### Further PDF documents

- 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/

2

# Foreword | Smoking - A Global Overview 1/3





# **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 worldwide<sup>2</sup>

#### **Environment**

- 600 million trees
- 200,000 hectares of land
- 22 billion tons of water
- 84 million tons of climate-damaging CO2<sup>3</sup>



### Examples Smokers in different countries



Every year, an estimated **4.5 trillion** 

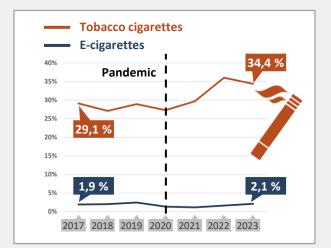
cigarette butts with more than 7,000 toxic chemicals end up in the environment.4,5,6



Source: https://www.van-grunsteyn.com/sektoranalyse-tabak-resilienz-durch-anpassung
 Source: https://www.paho.org/en/topics/tobacco-control
 Source: https://www.paho.org/en/campaigns/world-no-tobacco-day-2022

Source: https://www.nabu.de/natur-und-landschaft/aktionen-und-projekte/meere-ohne-plastik/29901.html
 Source: https://www.euwid-recycling.de/news/wirtschaft/jaehrlich-werden-45-billionen-zigarettenstummel-weggeworfen-170522/
 Source: https://www.euwid-recycling.de/fileadmin/data/euwid\_recycling\_und\_entsorgung/news/images/Talking\_Trash\_EN.pdf

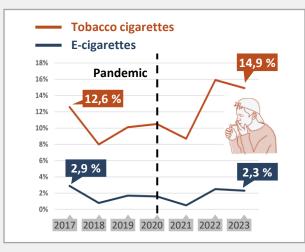
Since the pandemic, the number of people smoking tobacco cigarettes has skyrocketed.



DEBR/ Deutsche Befragung zum Rauchvert		German survey on smoking behaviour		
Population 14 y	ears +			
Measurement time			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	

Α

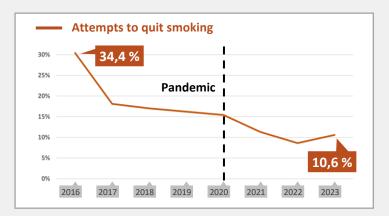
**Unfortunately, the number** of young smokers has risen just as sharply since the pandemic.



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

> **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.<sup>2</sup>



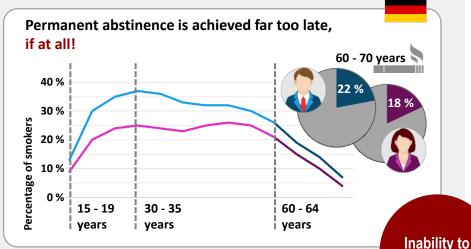


# What the politicians say:

**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."<sup>3</sup>

# Foreword | The Problem - Inability to Abstain 3/3



Inability to abstain

### Current S3 guideline<sup>1</sup>

"... 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) "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."<sup>2</sup>

Anil Batra

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



"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." <sup>3</sup>

Stephan Mühlig Head of the Psychotherapeutic University Outpatient Clinic TU Chemnitz

TU Chemnitz

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/Entwoehnung-kommt-oft-viel-zu-spaet-409870.html

4) Source: https://www.bmbf.de/bmbf/shareddocs/interviews/de/iede-dritte-krebserkrankung-ist-vermeidbar.html

"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.**"<sup>4</sup>

Ute Mons

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



1) Source: https://register.awmf.org/assets/guidelines/076-006l\_S3\_Rauchen-\_Tabakabhaengigkeit-Screening-Diagnostik-Behandlung\_2021-03.pdf

# 1. CiQuit quickly explained

Die schrittweise **Rekonditionierung** der Tabakabhängigkeit





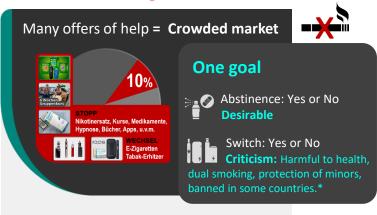


### Differentiation: "Covered need" vs. "CiQuit"

# 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"!



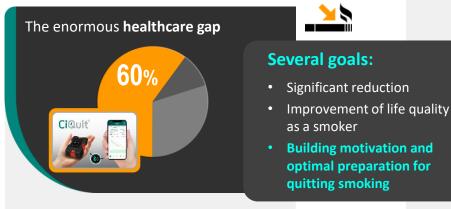
Only - **around 10%** - of smokers attempt to quit smoking each year or try switching to alternative products.\*

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

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### Smoke "less" first!



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 ..."<sup>1</sup>

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



# **Reaches smokers!**

> Psychological background: Rubicon model see: 3. Reaching smokers!

## 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."<sup>2</sup>

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

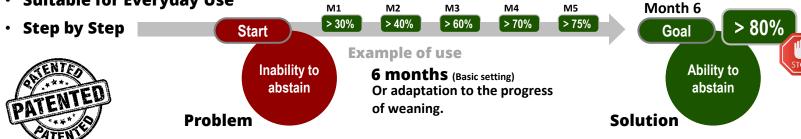
Ability to

abstain

# The product and the path to abstinence

# **Unlearn smoking - relearn non-smoking!**

- Digital
- Suitable for Everyday Use





### 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 via the display directly on the cigarette pack. Behaviour control

 $\approx$ 

Smoked

Available later

today

Just available



via therapy-controlled locking directly on the cigarette pack.

Hierarchical reduction

Al-generated therapy adjustments are transmitted from the app to the box.



#### Data measurement

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



### 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.



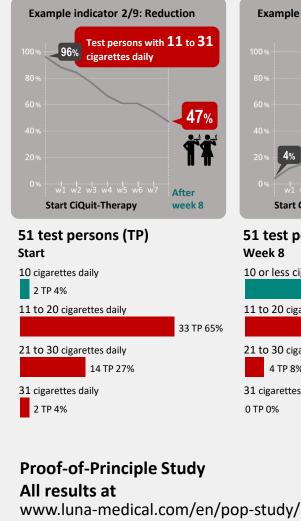
## **Proof-of-Principle Study (PoP-Study)**

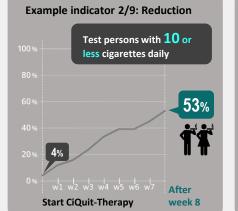
# The successful study



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

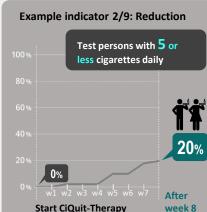


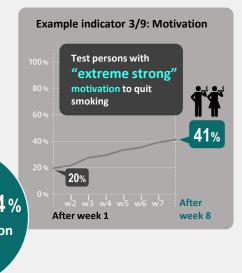


#### 51 test persons (TP) Week 8 10 or less cigarettes daily 27 TP 53% 11 to 20 cigarettes daily 20 TP 39% 21 to 30 cigarettes daily 4 TP 8% 31 cigarettes daily

0 TP 0%







### **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

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**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



Psychological (mental) dependence +

Inability to

abstain

Physical (bodily) dependence

### Addiction centre

#### Effects of nicotine withdrawal "Hungry nicotine receptors"

#### Agonizing craving

- Irritability and restlessness
  Frustration and anger
- Anxiety
- Sleep disorders

> Worth knowing

9. Status quo ...

- Concentration disordersDecreased heart rate
- Increased appetite and weight gain



High level of suffering

High relapse rates (despite help)

Next attempt to quit smoking is usually postponed for years



\*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

**Competitors focus on switching** 

to substitute products or

immediately

× 10%

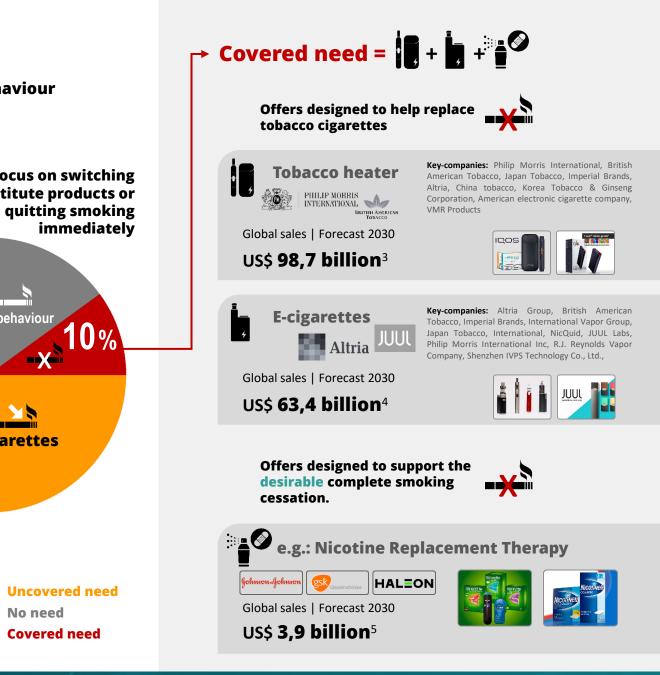
### That's what science says!

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### "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 guitting.<sup>1</sup>

30% No change in smoking behaviour World Health Organization Around 1.3 billion tobacco consumers 60% Global sales of tobacco products 1.000 in US\$ billion, forecast to 2025 900 Smoke "less" 800 tobacco cigarettes \$780 Tobacco heater first! 500 Over 1 billion people smoke Smokeless tobacco 400 the traditional E-cigarettes **CiQuit** tobacco cigarette 200 Cigars, cigarillos, tobacco Tobacco cigarettes 2015 2020 2025 University of Bath<sup>2</sup> Enormous **Uncovered** need healthcare gap No need **Covered** need



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 Source: https://www.verifiedmarketreports.com/product/heated-tobacco-products-htps-market-size-and-forecast/

Source : https://www.verifiedmarketreports.com/product/e-cigarette-and-vaping-market/

12 Source : https://www.researchandmarkets.com/reports/4968933/global-smoking-cessation-and-nicotine-de-addiction

# 2. Advantages for health insurance funds



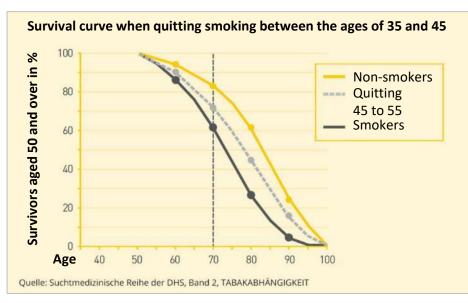




### Advantages for health insurance funds

# 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.<sup>1</sup>

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<b>Similar</b> Non-smoker	8 years	4,5 years			
Statistical regaining of years of life					
before the age of 35 between the ages of 35 and 45 between the ages of 35 and 45 between the ages of 35 and 45 ar					
Quit smoking					

# "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.<sup>3</sup>

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

### Current S3 guideline<sup>2</sup>

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

### Advantages for health insurance funds

# Enormous cost savings in the healthcare sector



### Current S3 guideline<sup>1</sup>

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"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)

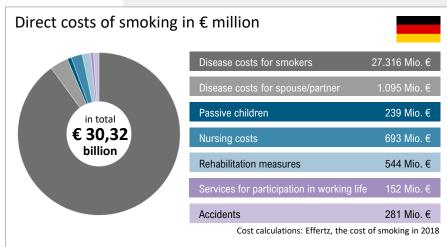
"Given the immense costs of treating tobacco-related diseases, the cost-effectiveness of such measures, which are located in the outpatient health care sector, has been sufficiently proven."

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

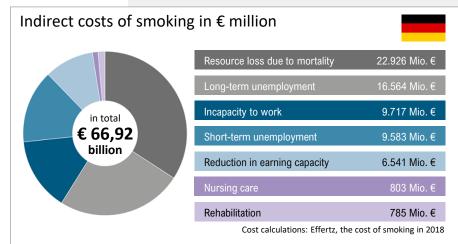
Thus, in Germany, **14.6% of the** total expenditures in the health sector are caused by tobacco smoking.

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.<sup>2</sup>



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



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

1) Source: https://register.awmf.org/assets/guidelines/076-006l\_S3\_Rauchen-\_Tabakabhaengigkeit-Screening-Diagnostik-Behandlung\_2021-03.pdf 2) Source: https://www.bundesregierung.de/breg-de/service/publikationen/drogen-und-suchtbericht-2019-1688896

15

# **Reach smokers!**

### Non-smoking courses are very rarely utilized!<sup>1</sup>

	Benefits from statutory health insurance						
Spitzenverband	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%	

Why does CiQuit reach smokers?

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

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.**" <sup>1</sup>

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.<sup>2</sup>

# 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."<sup>3</sup>

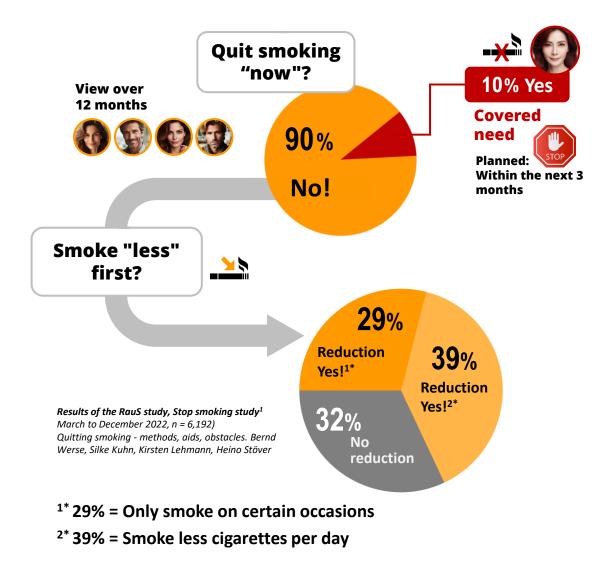
Prof. Dr. Anil Batra Head of the Department of Addiction Medicine and Addiction Research UK Tübingen

18

Source: https://www.bmbf.de/bmbf/shareddocs/interviews/de/jede-dritte-krebserkrankung-ist-vermeidbar.html
 Source: https://www.dhs.de/fileadmin/user\_upload/pdf/Broschueren/Suchtmedizinische\_Reihe\_Tabakabha%CC%88ngigkeit\_BFREI.pdf
 Source: https://www.dhs.de/fileadmin/user\_upload/pdf/Broschueren/Suchtmedizinische\_Reihe\_Tabakabha%CC%88ngigkeit\_BFREI.pdf

# CiQuit and the enormous healthcare gap

# **Uncovered need**



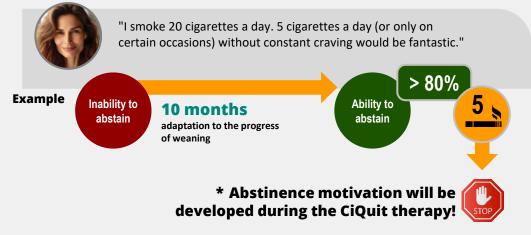


## ... for the unfulfilled desire

### 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!<sup>1</sup>

#### Ineffectiveness

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

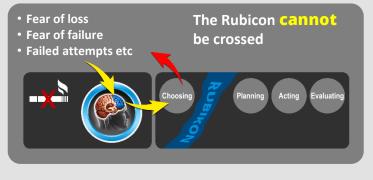
#### **Too time-consuming**

" 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



No, not now!

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#### **Rubicon model<sup>2</sup>**

### 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



# 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.

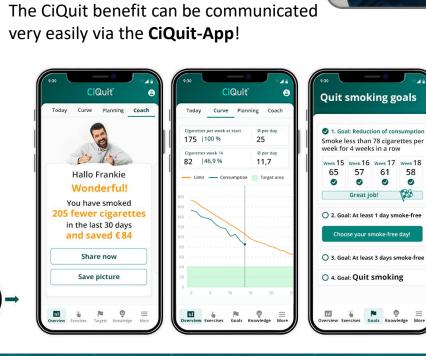
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# Visibility in the target group

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?





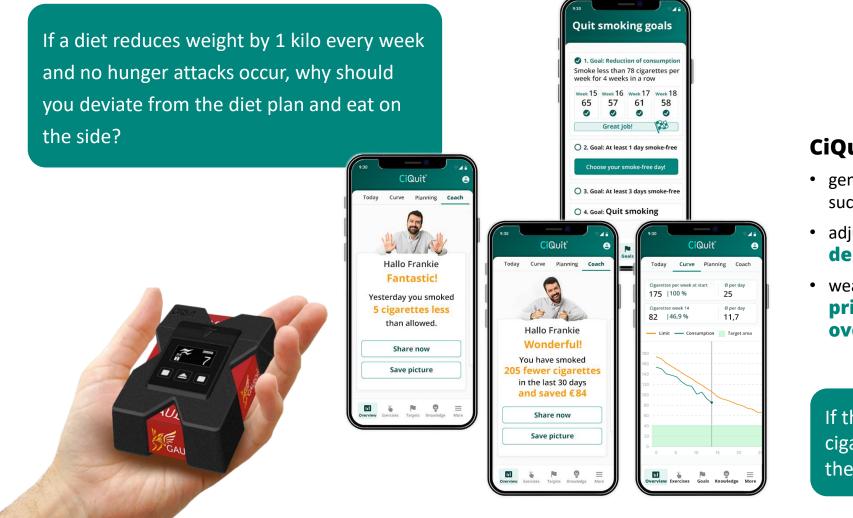


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# Why is the CiQuit-Box not bypassed?

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# 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 DiGA listing\***

or countries without DiGA

\*DiGA = Digital health application

**CiQuit- Status quo** See Appendix 1

# **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





§ 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



# Cooperation after DiGA listing\*

or countries with cost coverage

\*DiGA = **Digital health application** 

**CiQuit- Status quo** See Appendix 1

# **Health Insurance Funds**

# insured persons

- E-mail
- Internet info portal



Prescription e.g. via:

- Family doctor
- Tele doctor
- Company doctor





### Advantage health insurance funds





# **Internet info portal**

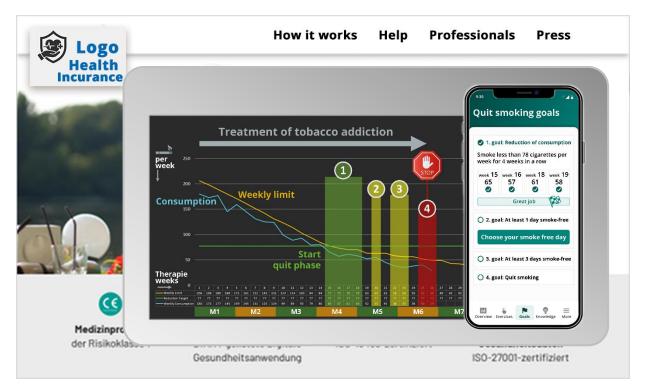
# Step 1: E-mail

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



# **Step 2: Internet info portal**

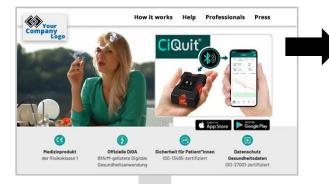
- Informationen
- Calculation of the individual weaning curve





# **Internet info portal**

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

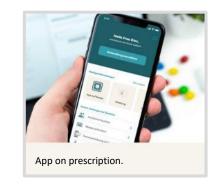


### With prescription

Setup video call to Tele-Doktor



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



### Printout 1-pager for family doctor

# **CiQuit**<sup>®</sup>

Reduction therapy for smoking cessation CiQuit ist eine Reduktionstherapie mit dem Ziel: Endgültiger Rauchstopp über Rekonditionierung und kognitiv-verhaltenstherapeutische Interventionen Tanangan Barkan Bar Barkan Barka Barkan Bark erreichen. Es basiert auf den S3-Leitlinien und bedient die Therapiesluien Ernährung, Bewegung und Verhalten. "zanadio" enthalten zanadio kann als einitige digitale Adipositas-Therapie von Patientlinnen mit direktem Support durch den Hersteller in Eigenenwendung eingesetzt werden. Als App ist zanadio 100 miles ederzeit und ortsunabhängig einsetzbar. Koston und Abrochnung zanadio ist ein Medizinprodukt und wurde durch das Bundesinstitut für Arzneimittel und Medizinprodukte cepr0ft und als Digitale Geeundheitsanwendung (DKGA) in die Liste verordnungsfähiger Produkte aufgenommen. zanadio ist eine Regelleistung ohne Zuzahkung aller gesetzlichen Kassen. Die Verordnung erfolgt extrabudgetär nd belastet daher weder Arznei- noch Heilmittelbu 
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MEDICAL

# Without prescription

Link for direct enquiry to health insurance funds

All statutory health insurance funds and the first private health insurance funds cover the costs of DiGA

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- 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!

# A wide range of Offers of Help













SWITCH E-cigarettes Tobacco heater



Tobacco heate E-cigarettes









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# 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 longlasting.
- I will gain weight.

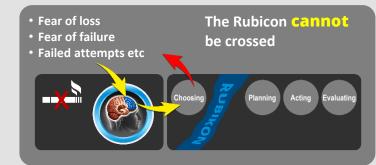
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 at best, I will become a lust-hostile, uncomfortable, boring and militant nonsmoker.



Fear of losing something "precious"!

- Long decision-making process
- High persuasion effort



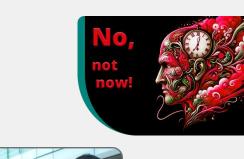
### No, not now!











# 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.

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:

**CiQuit-**

therapy

Reduction

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



### Non-smoking courses are very rarely utilized!<sup>1</sup>

	Benefits from statutory health insurance						
	Individual behavioural prevention						
Spitzenverband	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://gkvspitzenverband.de/krankenversicherung/praevention \_selbsthilfe\_beratung/praevention\_und\_bgf/praeven tionsbericht/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%.<sup>10</sup> Intensive interventions with multiple contacts before and after the quit date achieve higher abstinence rates.<sup>11</sup>

2) Source: https://www.dhs.de/fileadmin/user\_upload/pdf/Broschueren/Suchtmedizinische\_Reihe\_Tabakabha%CC%88ngigkeit\_BFREI.pdf

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

Source: https://register.awmf.org/assets/guidelines/076-006l\_S3\_Rauchen-\_Tabakabhaengigkeit-Screening-Diagnostik-Behandlung\_2021-03.pdf
 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/rauchentwoehnung/koennen-nikotinpflaster-und-co-bei-der-rauchentwoehnung-helfen 8) Source: https://www.stiftung-gesundheitswissen.de/wissen/rauchentwoehnung/kann-vareniclin-bei-der-rauchentwoehnung-helfen



#### Success rates in tobacco cessation



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%.<sup>2</sup> Unassisted attempts to quit smoking succeed in only 3% to 5% of cases.<sup>3</sup>



≈ **10** %

≈ 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.<sup>4</sup> NichtraucherHelden-App (DiGA), study result: The NichtraucherHelden-App doubles the abstinence rate.<sup>5</sup>



#### **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).<sup>6</sup> 16%, die NET nutzten, rauchten nicht mehr. 11%, die ein Placebo verwendeten, rauchten nicht mehr.<sup>7</sup>



≈ 25 %

≈ 15 %

#### Medication e.g.: Champix, Zyban

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



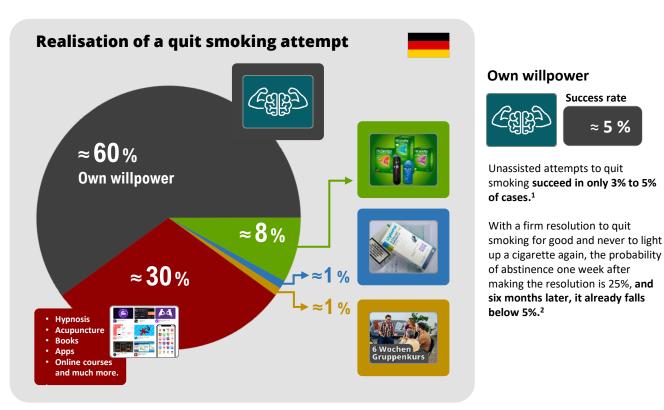
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# **Relying only on willpower - The wrong strategy**

# **Problem**

A

Attempts to quit smoking on one's own willpower despite a very low success rate, as many smokers overestimate their ability to guit 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.



### Important! S3 guideline<sup>3</sup>

"Unlike many other health interventions, individuals seeking to guit 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

Success rate

≈ 5 %

#### **Replacement Therapy**



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

#### Do nicotine replacement products help to guit smoking? <sup>5</sup>

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-nikotinpflaster-und-co-bei-der rauchentwoehnung-helfen

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

# **CiQuit: No or only low barriers to utilisation**

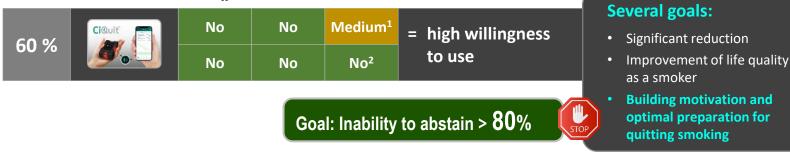
	High willingness to use							
	Low willing	ness to us	e	Ex	ample Germany			
Target group	Method of implementation	Effort during use	Side effects	Costs	Use of the method in %	Quit smoking attempts per year	Success rate	

### **Covered need - quit smoking "now"!** (Methods with high evidence)



#### **Uncovered need - Smoke "less" first!**

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

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

### **Current S3 guideline<sup>1</sup>**

"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 quideline: p. 97, para. 3, sentence 1)

### **Comparison of countries<sup>2</sup>**

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



Cost coverage NO

#### Using NRT during an attempt to quit smoking



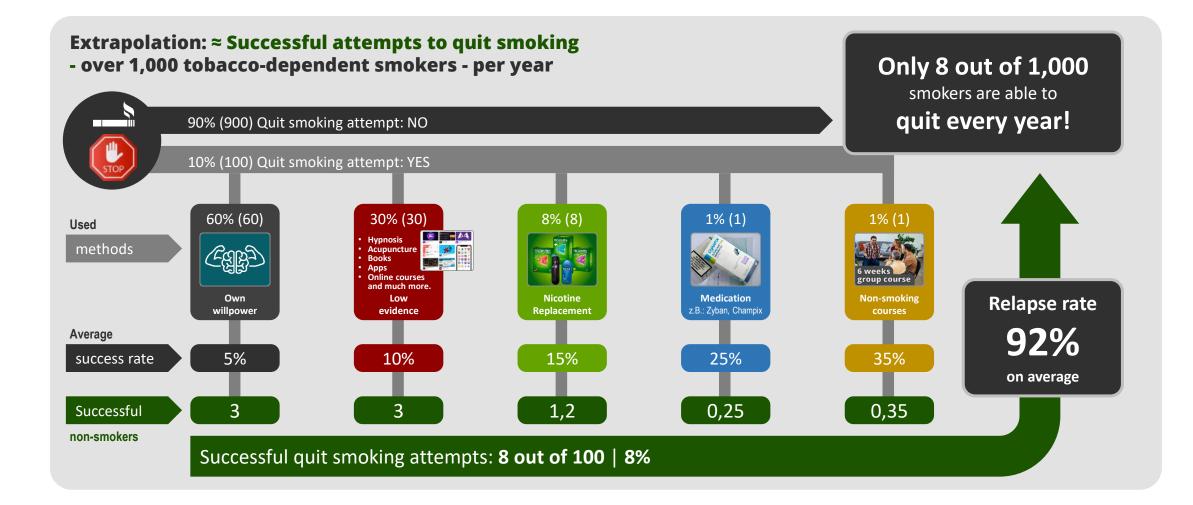
Cost coverage **YES** 

# 48%

Using NRT during an attempt to quit smoking

# High relapse rates despite many offers of help

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

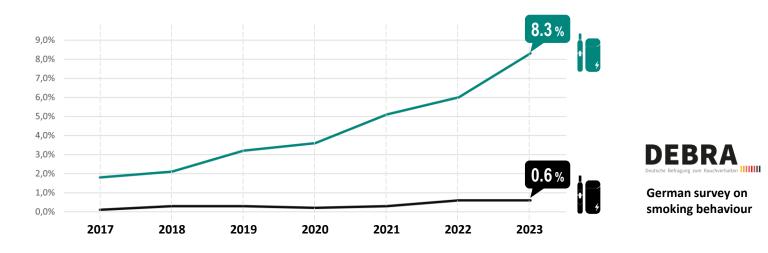


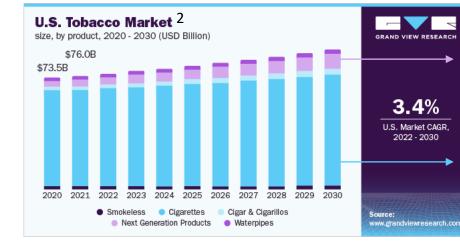


# Tobacco heaters (IQOS & Co.) - Germany as an example

### 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.<sup>1</sup>







#### 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 ecigarettes 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

# Thank you very much



#### Contact

#### Andreas Unsicker

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Yorckstr. 6 93049 Regensburg, Germany

### **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

Appendix 1: CiQuit and DiGA	38
Appendix 2: CiQuit and the DiGA directory	39
Appendix 3: The 9 key indicators	40
Appendix 4: CiQuit goals and the scientific derivation	41
Appendix 5: The scientific background to CiQuit	42
Appendix 6: Summary - The primary task of the CiQuit-Box	43
Appendix 7: Summary - The primary task of the CiQuit-App	44



# 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: CiQuit and DiGA**

# **CiQuit becomes DiGA**

DiGA = Digital **Health** Application

DiGA-Report 2022

The top 5 most common diseases that can currently be treated with a DiGA:

- Obesity/overweight around 37 million
- Smoking around 23 million
- · Back and spinal problems around 21 million,
- Sleep disorders around 21 million,
- Diabetes around 7 million

In the USA, where health insurers have been using digital therapies for a few years now, the general usage rate of DiGA across the various diagnoses was around 0.5 percent in 2020 and reached up to 2.5 percent for successful apps.

Let's assume that 0.5 percent of insured persons in Germany also use a

corresponding DiGA. With a current average price of €410 per quarter and a prescription period of two quarters, as recommended by the majority, this would result in costs of around €450 Mio. per year for these five indications alone.

### Cost coverage by health insurance funds

Cost coverage by health insurance funds in accordance with the German Digital Healthcare Act (DVG, "App on prescription", Sections 33a and 139e of the Fifth Book of the German Social Code)

### Bundesinstitut für Arzneimittel und Medizinprodukte BfArM confirmed 11.08.2023

# **3 Highlights**

- CiQuit box and CiQuit app will be reimbursed.
- Form of therapy: No immediate smoking cessation necessary, but slow reduction (keyword: harm reduction).
- No absolute abstinence rates are necessary for proof of efficacy.

Bundesinstitut für Arzneimittel und Medizinprodukte

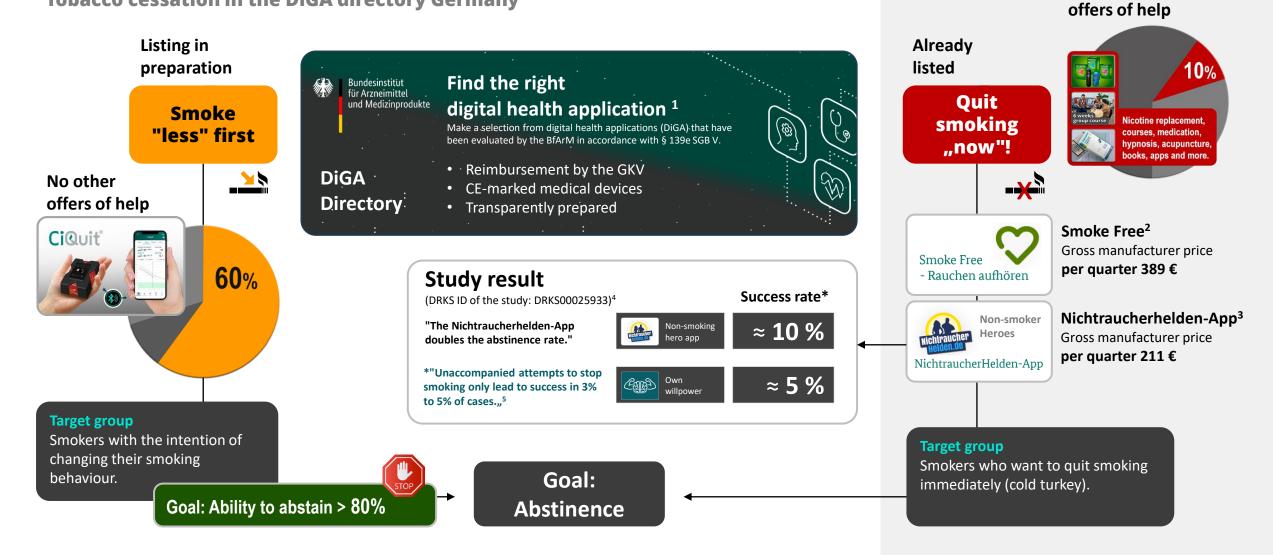
#### Ergebnisprotokoll zur Beratung nach § 23 DiGAV

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Angaben zur Beratung / Information on ad	vice
Verfahrensnummer/ Procedure number	2022-100
Produktname/ product name	CiQuit
Teilnehmende BfArM / Participants BfArM	<ul> <li>Anna Nickel, Gesprächsleitung</li> </ul>
	Innovationsbüro
	- Dr. Michael Bühlen, klinischer Assessor
	- Dr. Tobias Möllers , DiGA Assessor
	- Florian Strauch, DiGA Assessor
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	<ul> <li>Prof. Dr. Anil Batra, Universität Tübingen</li> </ul>
	- Dr. Eva Hoch, IFT
	<ul> <li>Dr. Larissa Schwarzkopf, IFT</li> </ul>
	<ul> <li>Pierre Jäger, Johner Medical</li> </ul>
	- Till Gladow, dmac
	<ul> <li>Cordula Forster, dmac</li> </ul>
	- Laura Brandt, dmac
the forest line on 1 Mars models	
Ihre Fragestellungen / Your questions	Position und Antwort des BfArM/ Position and
Frage 1: Stimmt das BfArM der	response of BfArM
	Ja, das BfArM stimmt grundsätzlich der
vorgeschlagenen Studiensynopse bezüglich des mN "Verbesserung des	vorgeschlagenen Studiensynopse zu. Folgende Aspekte werden als positiv bewertet:
des mN "Verbesserung des Gesundheitszustands" grundsätzlich zu?	Aspekte werden als positiv bewertet: 1. Standardisierte ärztliche Kurzintervention für
Gesundheitszustands grundsatzlich zu?	Interventionsgruppe und Kontrollgruppe bei
	Studieneinschluss.
	2. Eckpunkte der Studiensynopse:
	Das BfArM unterstützt den Ansatz der Harm-
	Reduction bzw. Reduktion in Verbindung mit dem
	Motivationsaufbau zum Rauchstopp-Versuch und
	die Vermeidung eines zu früh festgelegten
	Rauchstopptages.
Frage 2: Zum Nachweis der Verbesserung des	Ja, das BfArM stimmt zu, dass ein signifikanter
Gesundheitszustands dient der Endpunkt der	Unterschied der Abstinenzrate zwischen
7-Tage-Punktprävalenz, validiert über Cotinin-	Interventions- und Kontrollgruppe, unabhängig
Messung. Als klinisch relevanter und für den	von der absoluten Abstinenzrate der
Nachweis ausreichender Effekt wird ein	Interventionsgruppe ausreichend für einen
signifikanter Unterschied der Abstinenzrate	klinischen relevanten Effekt ist.
zwischen Interventions- und Kontrollgruppe	



# Appendix 2: CiQuit and the DiGA directory

**Tobacco cessation in the DiGA directory Germany** 



# LUNAMEDICAL

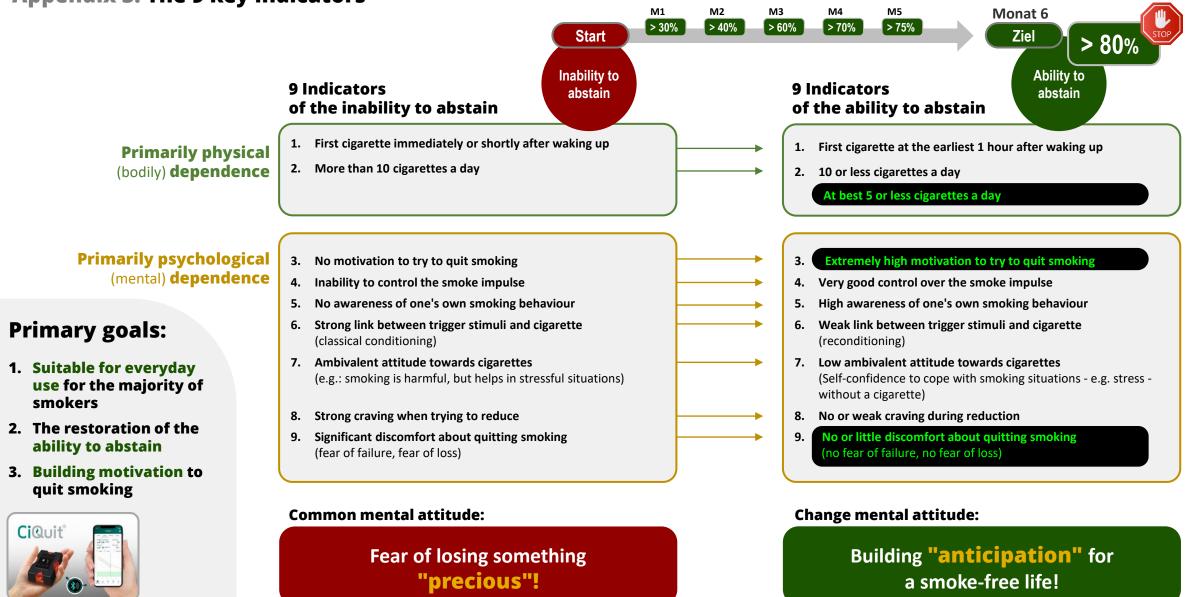
Source: https://diga.bfarm.de/de
 Source: https://diga.bfarm.de/de/verzeichnis/01909/fachkreise
 Source: https://diga.bfarm.de/de/verzeichnis/01085/fachkreise

4) Source: https://drks.de/search/de/trial/DRKS00025933 | Basic results | Conclusions 5) Source: https://www.aerzteblatt.de/pdf.asp?id=221166 | Trial and failure

Many other

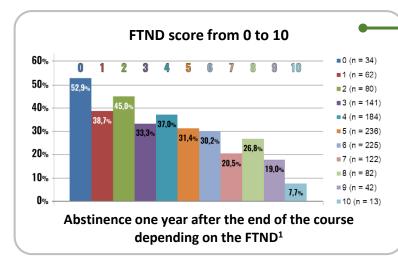
# **Appendix 3: The 9 key indicators**

. U N A



# **Appendix 4: CiQuit goals and the scientific derivation**

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





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

#### Result: The lower the

### physical dependence,

the more likely the participant is to be a nonsmoker one year after the end of the course.<sup>2</sup>



**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).

# 9 CiQUit<sup>®</sup>goals

Abstinenz-Fähigkeit



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)
- 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)

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.<sup>3</sup> 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

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41

# Appendix 5: The scientific background to CiQuit

# A core principle from science

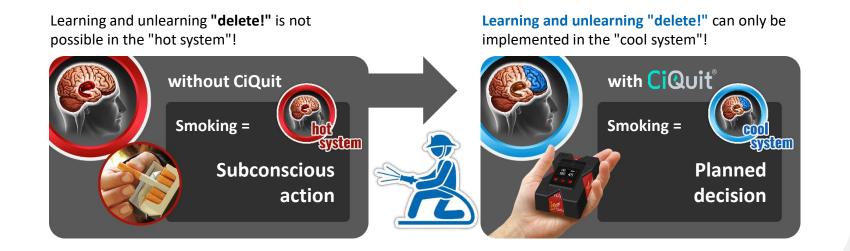
"Successful smoking cessation depends on how the learned habit of smoking can be permanently "deleted!" from the relevant brain area."

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



### 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!



# 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:

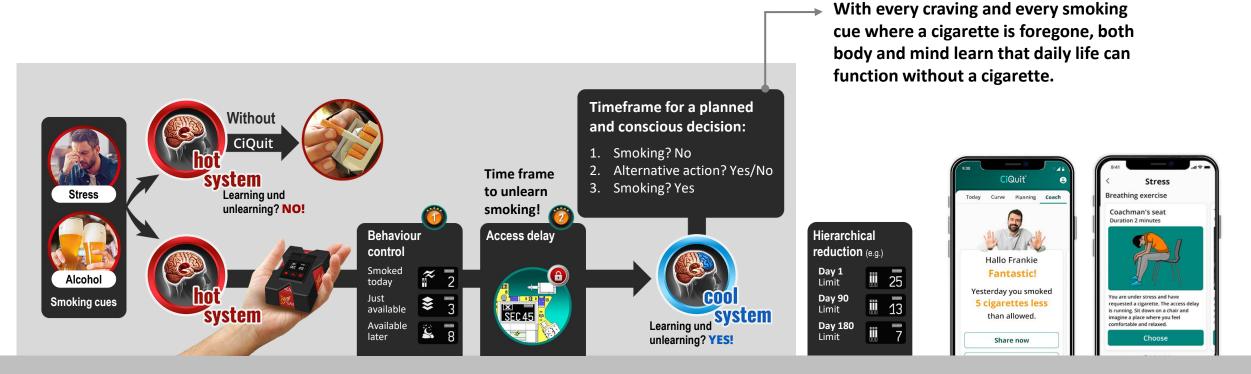
The "cool system" is analytical and future-oriented. It considers long-term consequences and health risks associated with smoking.

- 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 6: 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.



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.
- **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.



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.



# The CiQuit-App

Permanent maintenance of motivation and Al-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 massages**, 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."

