



Smoking - A Global Overview



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World Health
Organization

Tobacco consumption

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

Further PDF documents

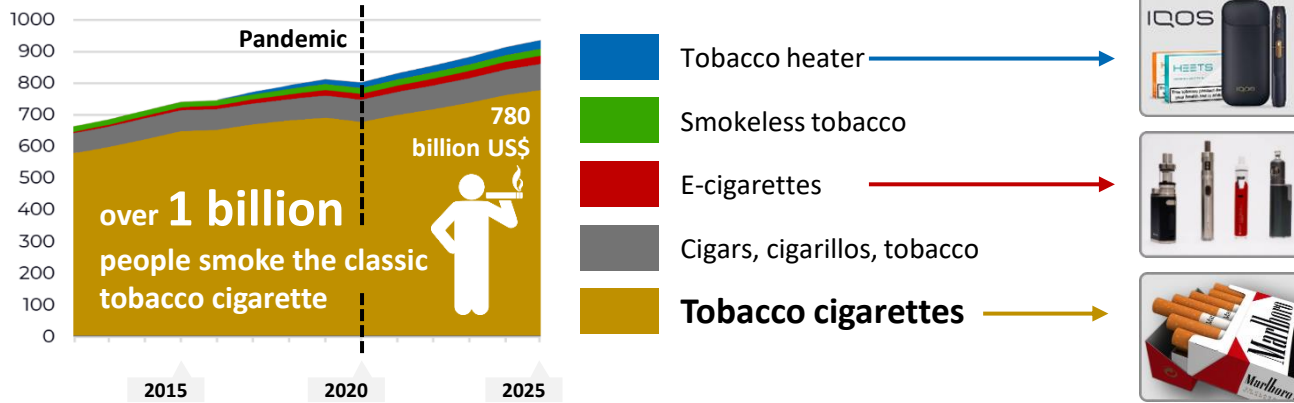
- **The scientific background**
<https://www.luna-medical.com/en/scientific/>
- **The proof-of-principle study**
<https://www.luna-medical.com/en/pop-study/>
- **The patent**
<https://www.luna-medical.com/en/patent/>
- **Cooperations with companies**
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<https://www.luna-medical.com/en/health-insurance/>
- **Cooperations with pharmaceutical companies**
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- **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



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	

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



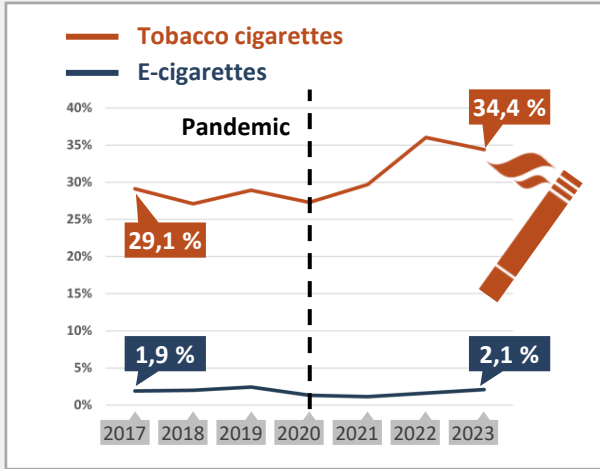
Every year, an estimated **4.5 trillion** cigarette butts with more than 7,000 toxic chemicals end up in the environment.^{4,5,6}

1) Source: <https://www.van-grunsteyn.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>

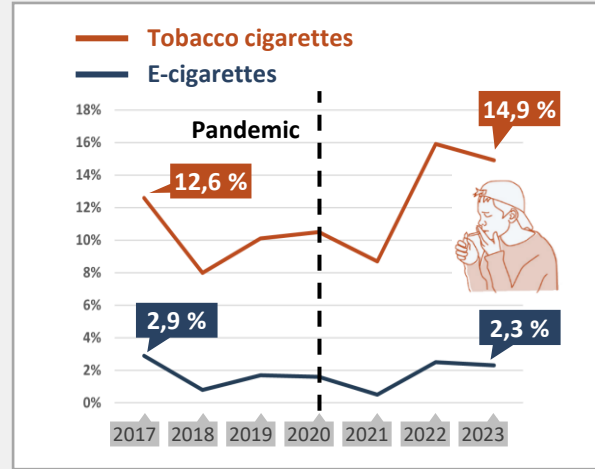
4) Source: <https://www.nabu.de/natur-und-landschaft/aktionen-und-projekte/meere-ohne-plastik/29901.html>
5) Source: <https://www.euwid-recycling.de/news/wirtschaft/jaehrlich-werden-45-billionen-zigarettenstummel-weggeworfen-170522/>
6) Source: https://www.euwid-recycling.de/fileadmin/data/euwid_recycling_und_entsorgung/news/Images/Talking_Trash_EN.pdf

Foreword | The Development of Smoking Germany as an example 2/3

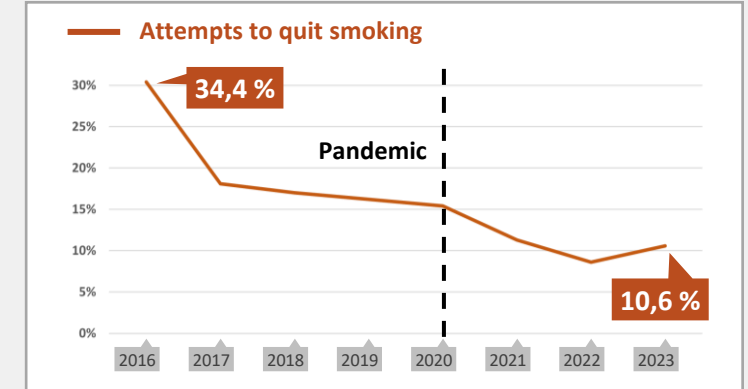
Since the pandemic, the number of people smoking tobacco cigarettes has skyrocketed.



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



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



DEBRA 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

"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



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

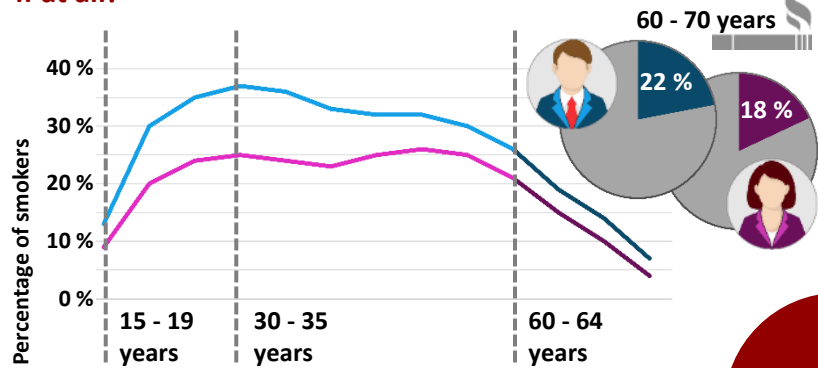
1) Source: <https://www.n-tv.de/panorama/Immer-mehr-Deutsche-greifen-zum-Glimmstaengel-article23366473.html>

2) Source: DEBRA study German survey on smoking behavior, <https://www.debra-study.info/>

3) Source: <https://www.aerzteblatt.de/nachrichten/141011/Hilfe-beim-Rauchsueg-Drogenbeauftragter-schlaegt-Anreize-fuer-Aerzte-vor>

Foreword | The Problem - Inability to Abstain 3/3

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



Inability to
abstain

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)

"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



"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



"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)



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/shareddocs/interviews/de/jede-dritte-krebserkrankung-ist-vermeidbar.html>

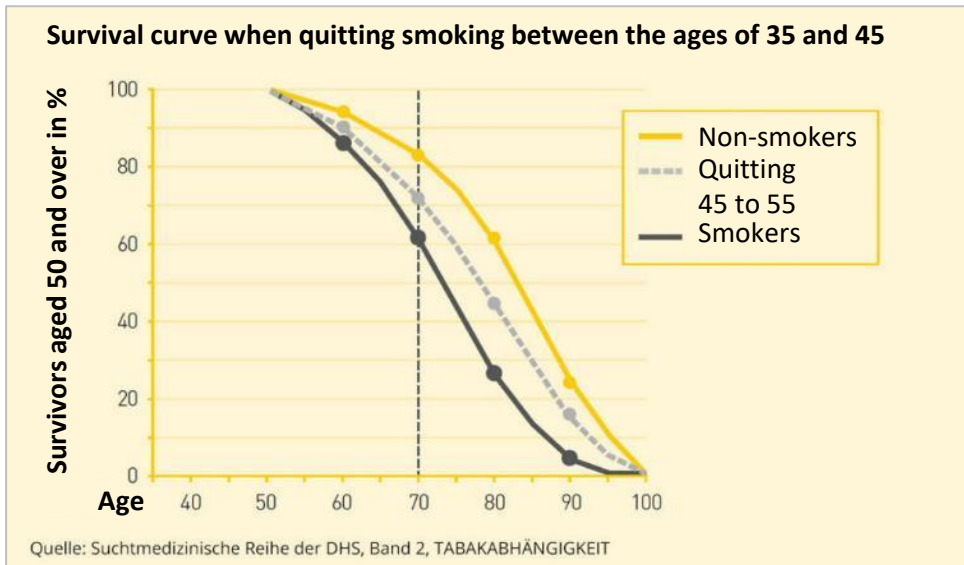
1. Health and economic savings

Germany as an example



1.1 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)

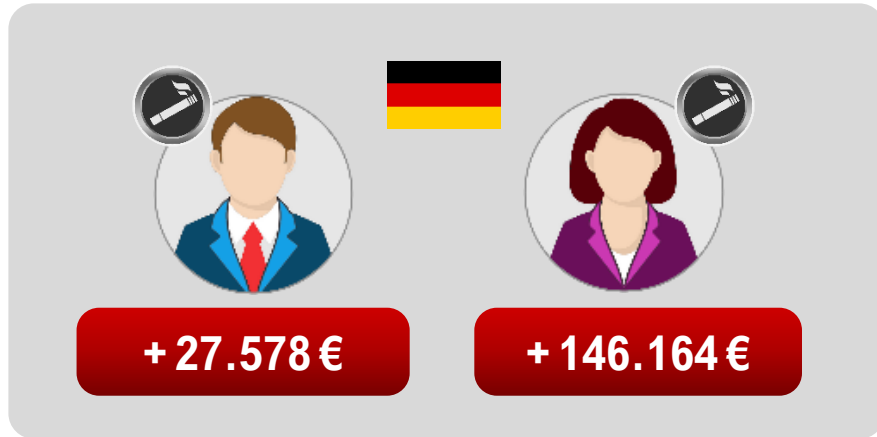
1) Source: Anil Batra, Peter Lindinger (2013) TABAKABHÄNGIGKEIT suchtmedizinische Reihe der DHS Band 2 |

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>

1.2 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."

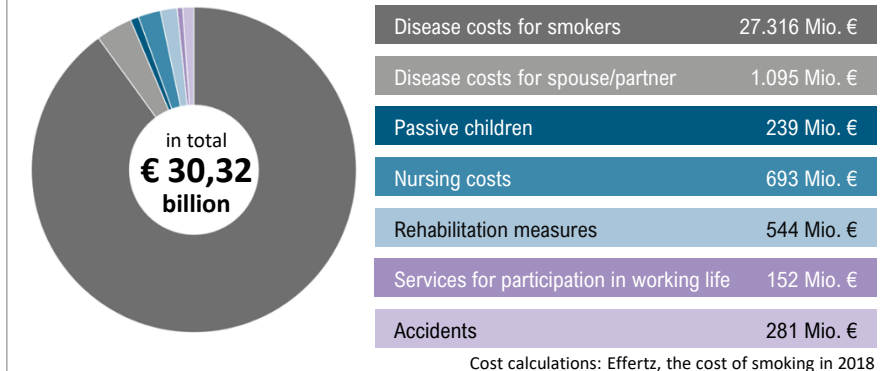
(S3 Guideline: p. 203, 4.9.8.1 Financing of tobacco cessation, sentence 4)

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.**

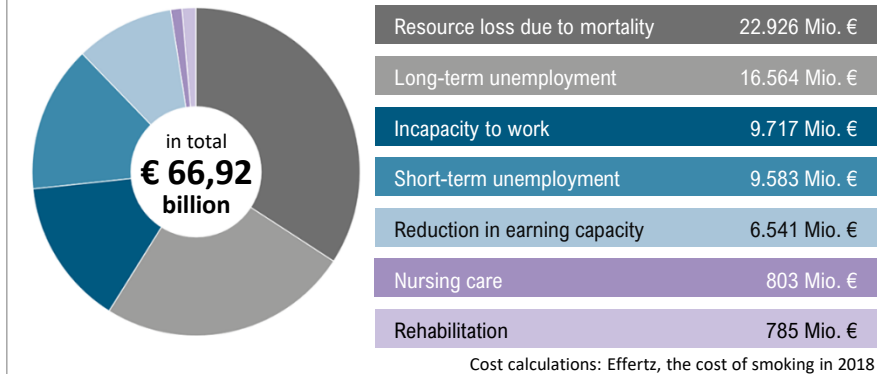
Additionally, intangible costs, such as limitations on quality of life or the suffering and pain of those affected, are estimated at around 99 billion euros per year.²

Direct costs of smoking in € million



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

Indirect costs of smoking in € million



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

1.3 Advantages from a business perspective

- Fewer days of absence due to illness.
- Increased productivity (including the avoidance of "smoke breaks").
- Prevention of loss of know-how due to early retirement or departure from the workforce.

Smokers are ill more often, less focused, and less productive – and they end up costing the employer a substantial amount of money.

Therefore, it is worthwhile to assist employees with quitting.

Quelle:

<https://www.cio.de/a/schnell-mal-eine-rauchen-ist-fuer-unternehmen-teuer,2918059>

Additional costs smokers vs. non-smokers

- Estimation: Bundesverband mittelständische Wirtschaft (BVMW)¹

2.000 € per year

- Recent study from the USA²

\$5,800 per year

- Study of the US CDC³

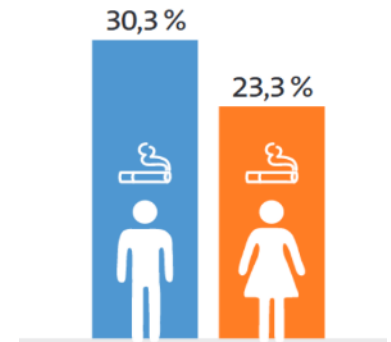
The U.S. Centers for Disease Control and Prevention (CDC) estimate the costs (in 2008) for each smoking employee at approximately

\$3,390 per year,

with \$1,760 in lost productivity and \$1,630 in excess medical expenditures.

Proportion of men and women who smoke

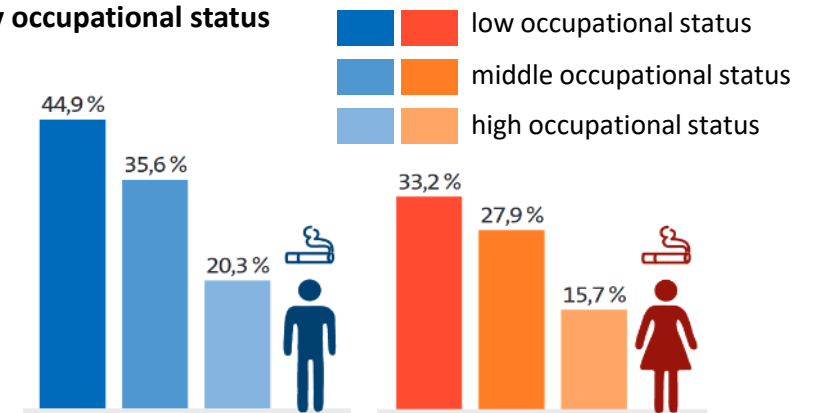
by participation in the working life



Source: Tobacco Atlas Germany 2020, DKFZ, German Cancer Research Centre

Employed persons

by occupational status



1) Source: <https://www.deutschlandfunknova.de/beitrag/teure-raucher-was-raucher-die-deutsche-wirtschaft-kosten>

2) Source: <https://www.spiegel.de/wirtschaft/us-studie-raucher-kosten-arbeitgeber-5800-dollar-mehr-im-jahr-a-903558.html>

3) Source: <https://no-smoke.org/business-costs-smoke-filled-environment/>

2. Overview: Covered need vs. CiQuit



Differentiation: "Covered need" vs. "CiQuit"

The problem

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

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

Quit smoking "now"!

Many offers of help = Crowded market



One goal

Abstinence: Yes or No
Desirable

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

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

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

= **Covered need**

Smoke "less" first!

The enormous healthcare gap



Several goals:

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

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

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

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

= **Uncovered need**

What addiction experts say!

"Reduction treatments ...

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

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

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

USP: 
Smoke "less" first!

Reaches smokers!

- > **Psychological background: Rubicon model**
See Worth knowing:
7. CiQuit - Rubicon model: The quick decision to use

*see Worth knowing: 8. Tobacco heaters (IQOS & Co.) - Germany as an example

**see Worth knowing: 9. Success rates in tobacco cessation

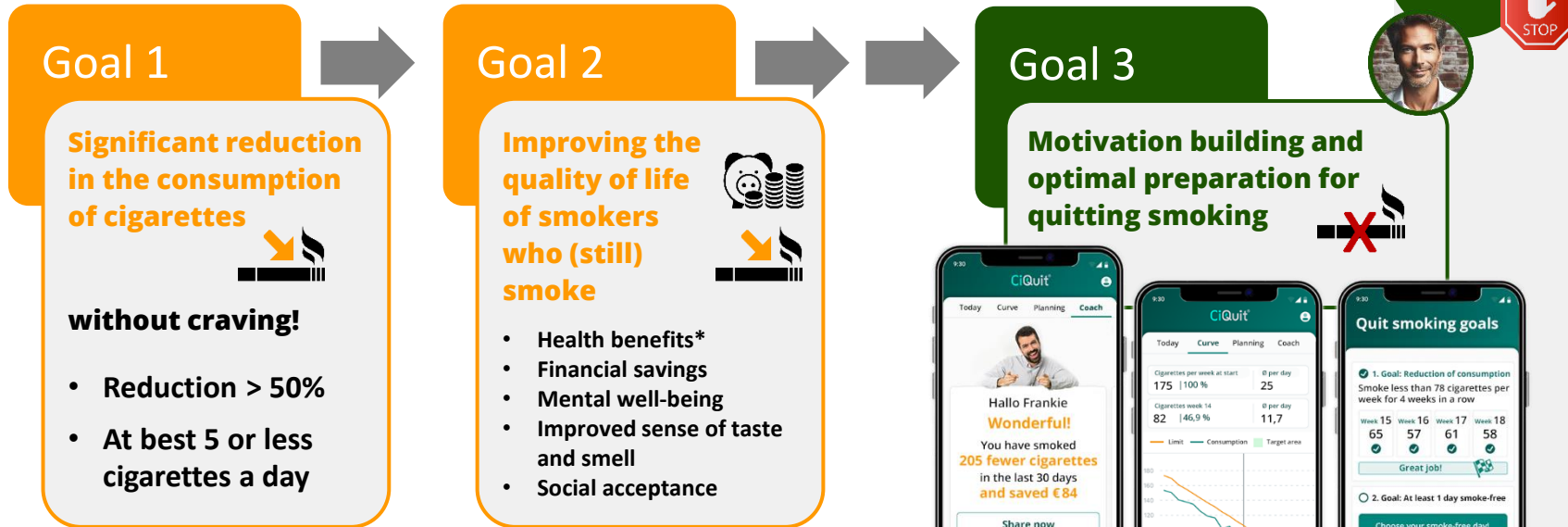
1) Source: <https://docplayer.org/45668034-4-1-das-paradigma-zieloffener-suchtarbeit.html> | S. 198

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**.

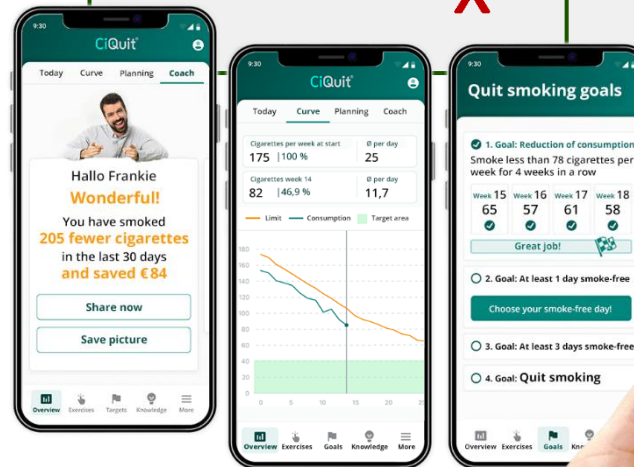


What addiction experts say!

"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."²

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



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

Reconditioning with CiQuit-Box and CiQuit-App



CiQuit®
Reconditioning



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



The reduction of smoking ...

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

1) Source: https://ensp.network/wp-content/uploads/2020/10/guidelines_2020_english_forprint.pdf | S. 91 ff
2) Source: <https://www.google.com/search?q=20.+t%C3%BCbinger+suchttherapie+2015+suchttherapie+im+wandel+der+letzten+zwei+jahrzehnte+client>

Large uncovered need

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

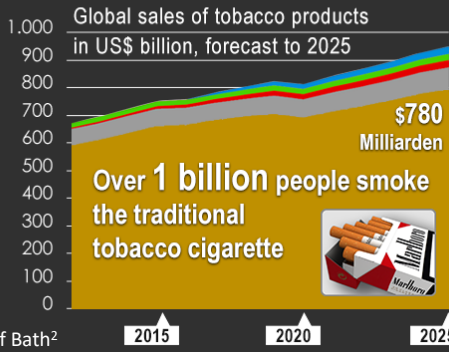
That's what science says!

"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

World Health Organization
Around 1.3 billion tobacco consumers



- Tobacco heater
- Smokeless tobacco
- E-cigarettes
- Cigars, cigarillos, tobacco
- Tobacco cigarettes**



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, NicQuit, 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

Key-companies: Johnson & Johnson, gsk GlaxoSmithKline, HALEON

Global sales | Forecast 2030
US\$ 3,9 billion⁵

1) Source: Quelle: https://edoc.uni-muenchen.de/22126/1/Kiss_Alexa.pdf
2) Source: <https://www.van-grunsteyn.com/sectoranalyse-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>

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

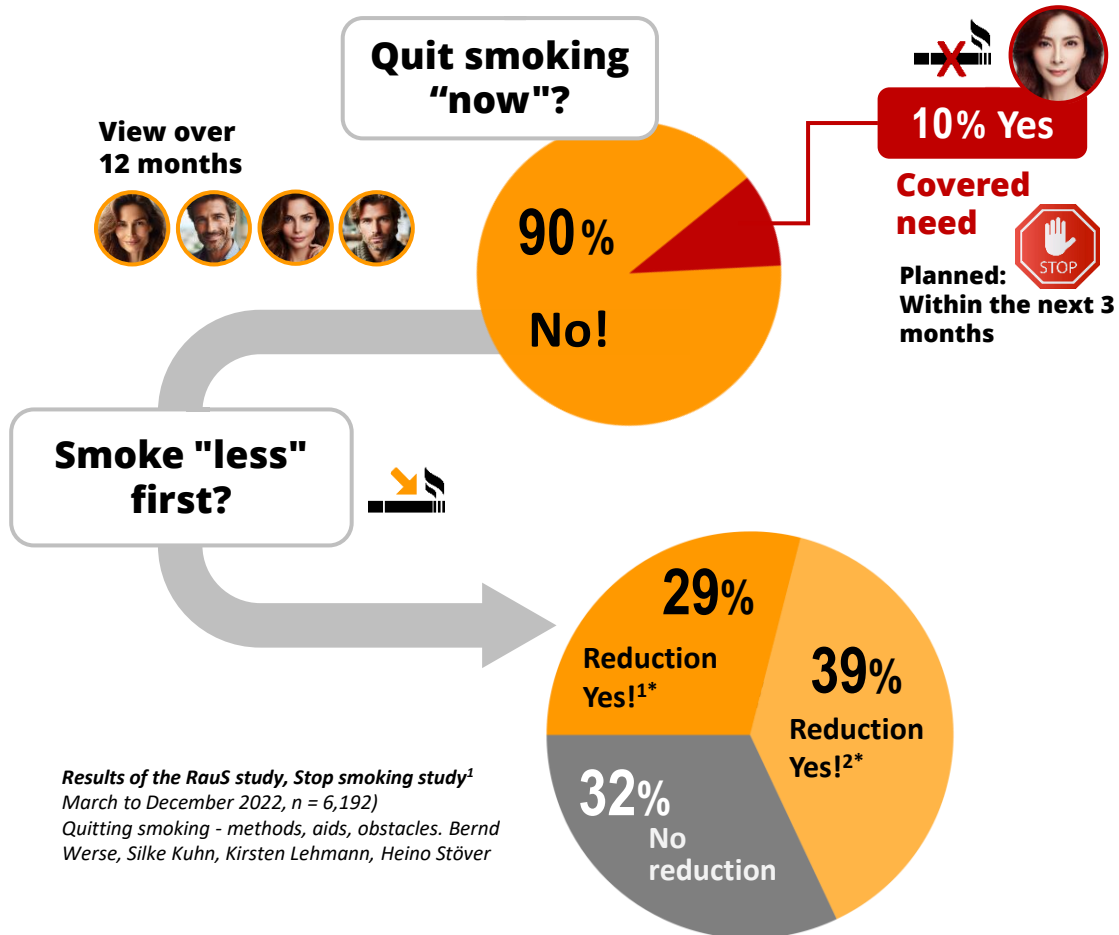
Correct is ...

- "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



Results of the RauS study, Stop smoking study¹
 March to December 2022, n = 6,192)
 Quitting smoking - methods, aids, obstacles. Bernd
 Werse, Silke Kuhn, Kirsten Lehmann, Heino Stöver

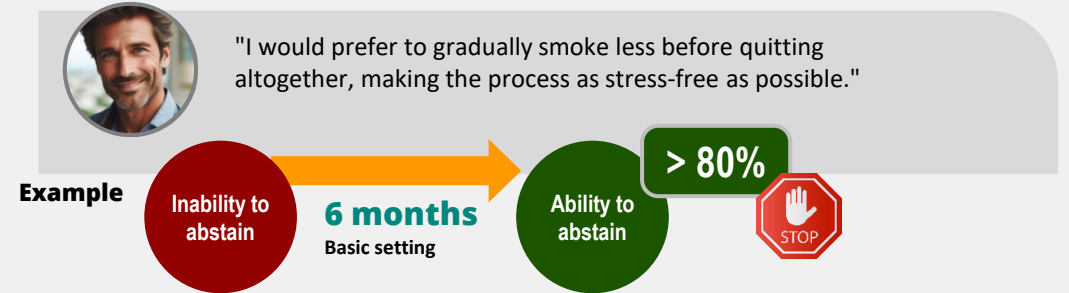
1* 29% = Only smoke on certain occasions

2* 39% = Smoke less cigarettes per day

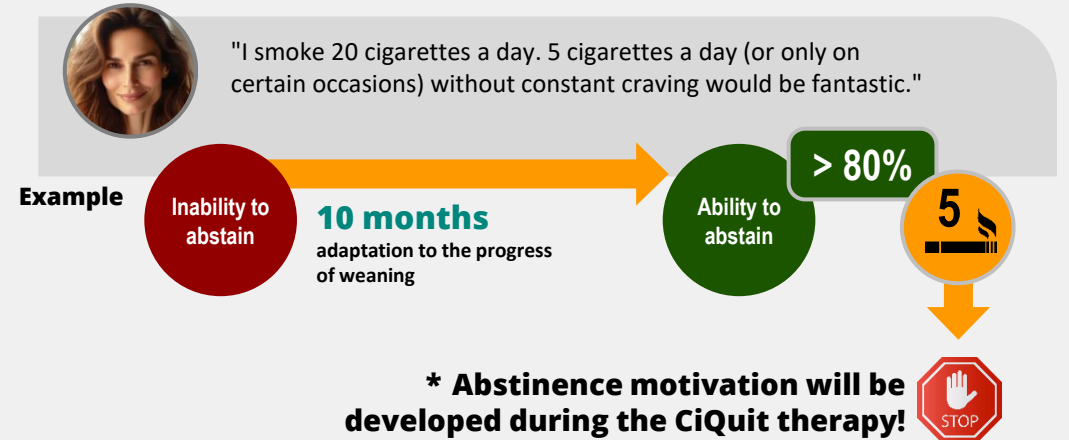


... for the unfulfilled desire

1. The gentle introduction to smoking cessation



2. The permanent reduction of consumption*



1) Source: https://www.frankfurt-university.de/fileadmin/standard/ISFF/Zigarette__Werse.pdf

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."

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.

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.

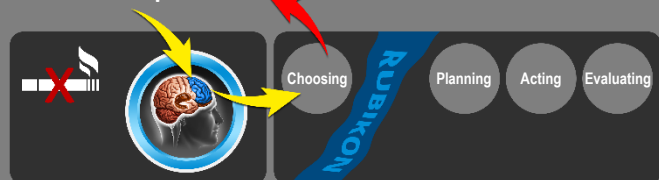
Quit smoking "now"!

**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!

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!


1) Source: <https://www.aerzteblatt.de/pdf.asp?id=221166> | Versuch und Scheitern
2) Source: <https://studyflix.de/biologie/rubikon-modell-5221>

CiQuit: No or only low barriers to utilisation

Barriers to utilizing offers of help





- **Effort**
- **Side effects**
- **Costs**

 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
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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	

Goal: Inability to abstain > 80%



Several goals:

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

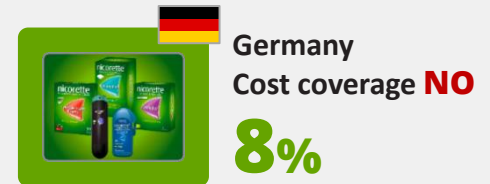
Current S3 guideline¹

“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.”

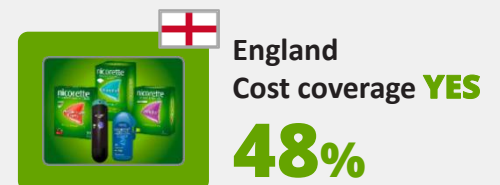
(S3 guideline: p. 97, para. 3, sentence 1)

Comparison of countries²

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



Using NRT during an attempt to quit smoking



Using NRT during an attempt to quit smoking

- 1) Attractive subscription model, 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>

Visibility in the target group

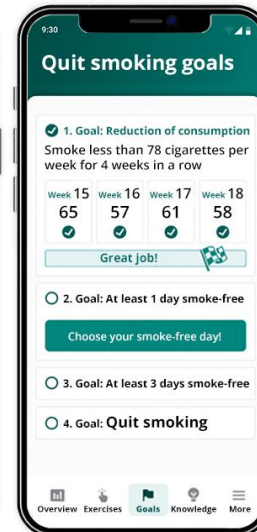
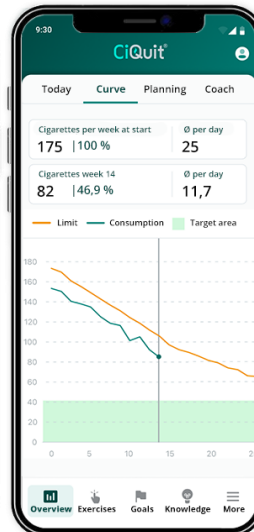
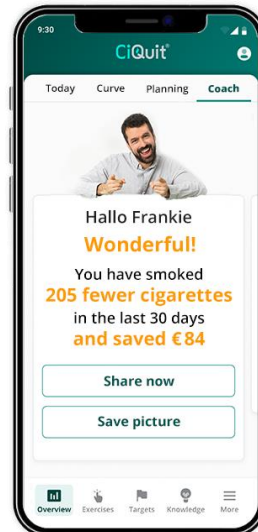
Experience shows that every CiQuit user is immediately approached by other smokers about the **CiQuit-Box**.

Other smokers are asking:

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

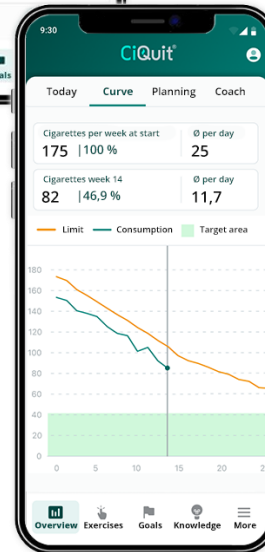
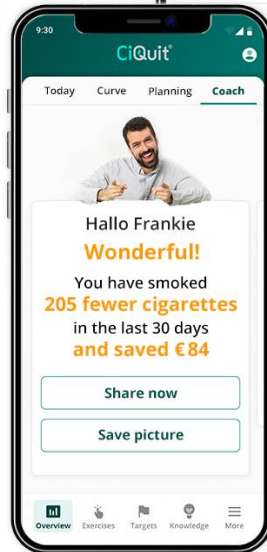
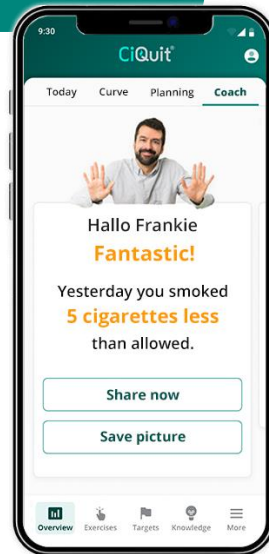


The CiQuit benefit can be communicated very easily via the **CiQuit-App**!



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

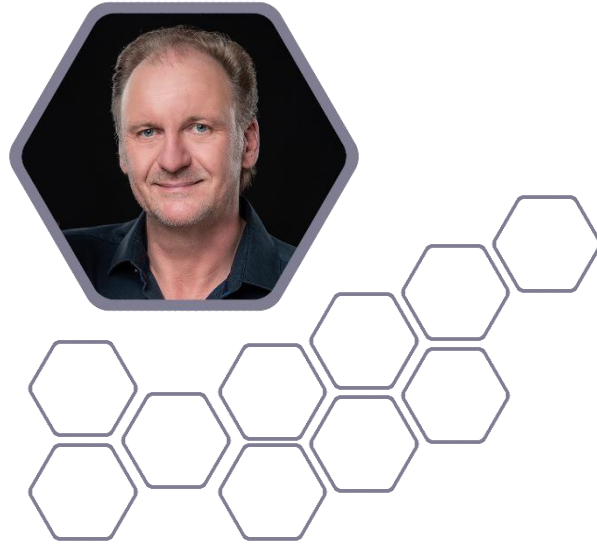


CiQuit

- 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.

Thank you very much



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What users say

Statements from the pilot study

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

Rainer W.

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

Astrid P.

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

Constanze K.

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

Stefan F.

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

Nils O.