



Cooperations with Pharmaceutical Companies



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Tabakkonsum

ist weltweit die größte
vermeidbare Ursache
für frühzeitige
Sterblichkeit.



Further PDF documents

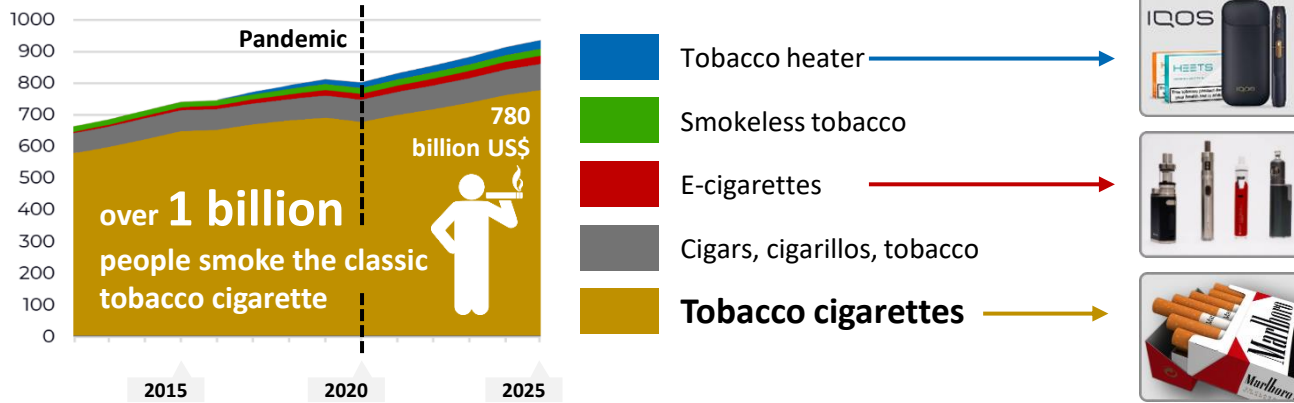
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- **The proof-of-principle study**
<https://www.luna-medical.com/en/pop-study/>
- **The patent**
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- **The covered need - Quit smoking "now"**
<https://www.luna-medical.com/en/covered-need/>
- **The 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



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	



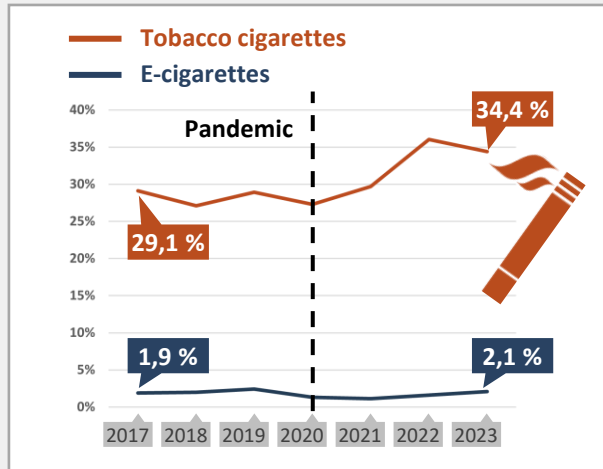
Every year, an estimated **4.5 trillion** cigarette butts with more than 7,000 toxic chemicals end up in the environment.^{4,5,6}

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

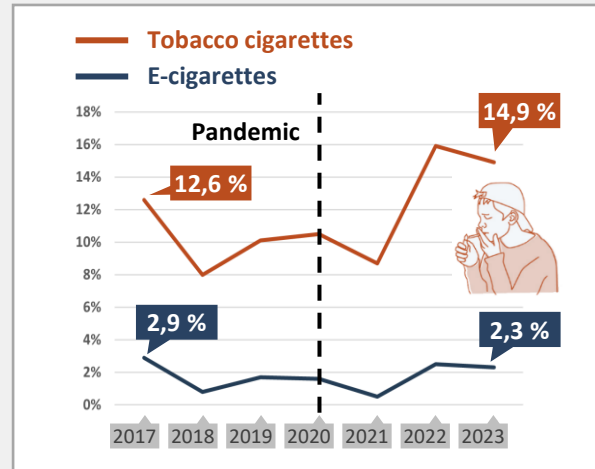
Foreword | The Development of Smoking Germany as an example 2/3

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



DEBRA Deutsche Befragung zum Raucherhalten			
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

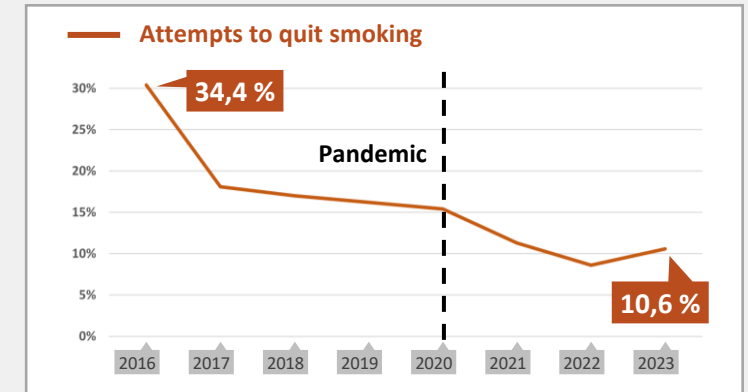
Unfortunately, the number of young smokers has risen just as sharply since the pandemic.



"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

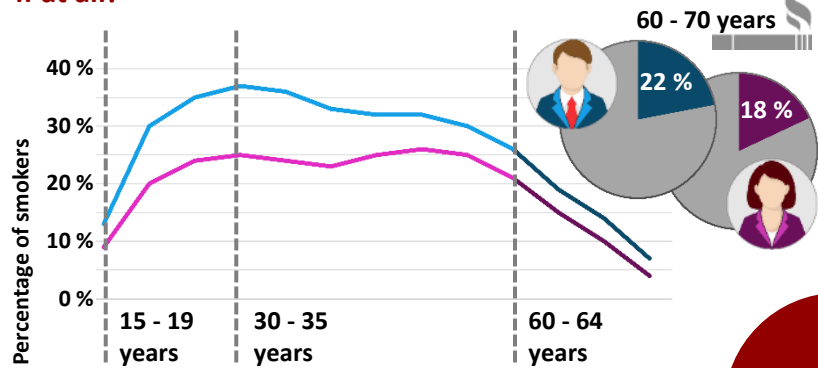
1) Source: <https://www.n-tv.de/panorama/Immer-mehr-Deutsche-greifen-zum-Glimmstaengel-article23366473.html>

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

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

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. 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: 2. Reaching smokers!

*see: 4. The status quo in tobacco cessation

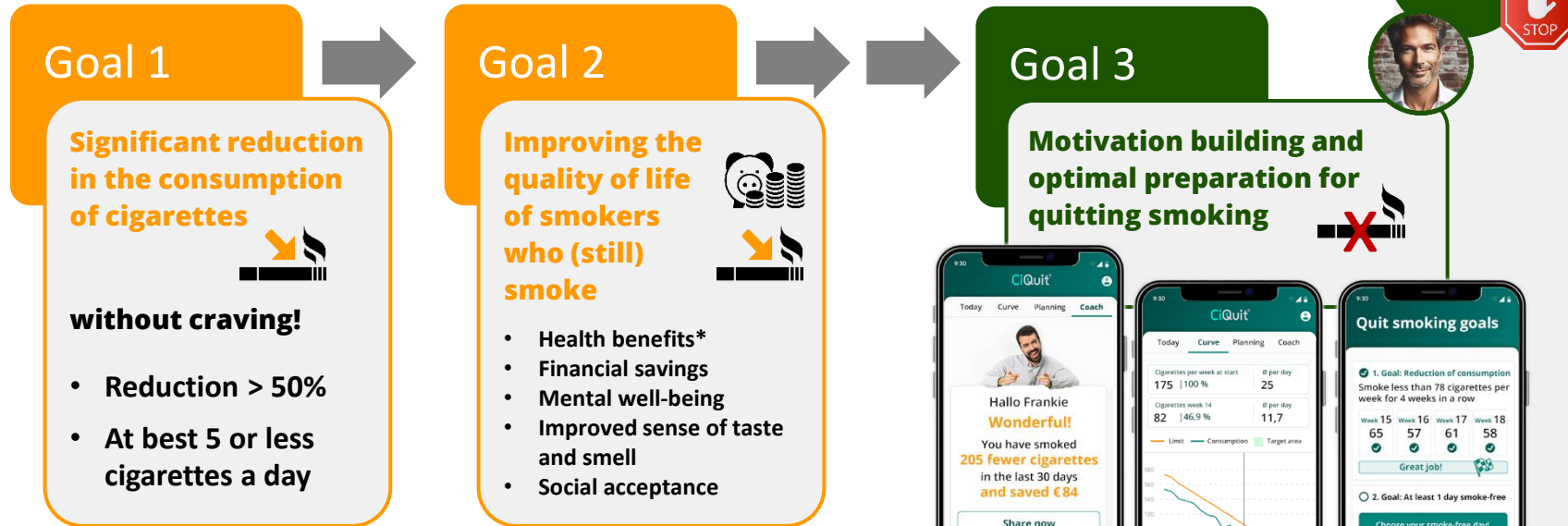
1) Source: <https://docplayer.org/45668034-4-1-das-paradigma-zieloffener-suchtarbeit.html> | S. 198

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**.



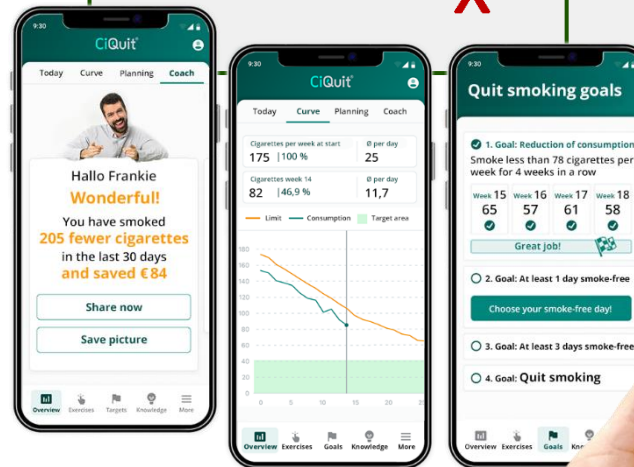
What addiction experts say!

"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



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



CiQuit®
Reconditioning



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

 **ENSP** European Network for Smoking and Tobacco Prevention

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

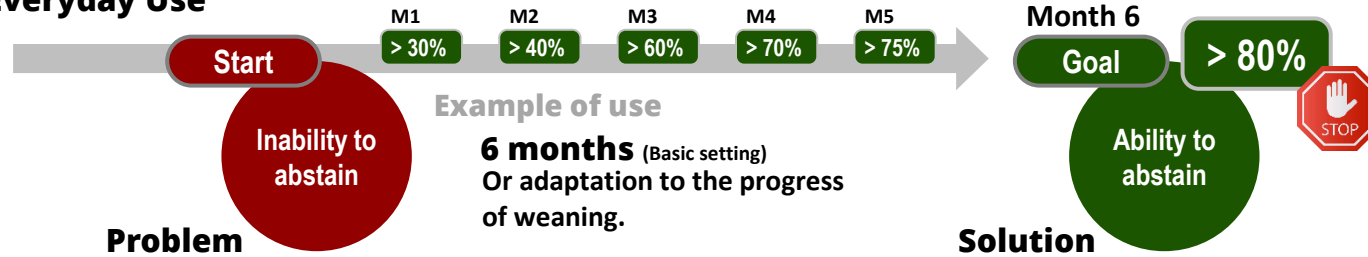
1) Source: https://ensp.network/wp-content/uploads/2020/10/guidelines_2020_english_forprint.pdf | S. 91 ff

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

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**

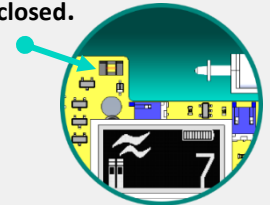
- The app - Permanent **maintenance of motivation** and AI-supported roadmap to abstinence!

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.

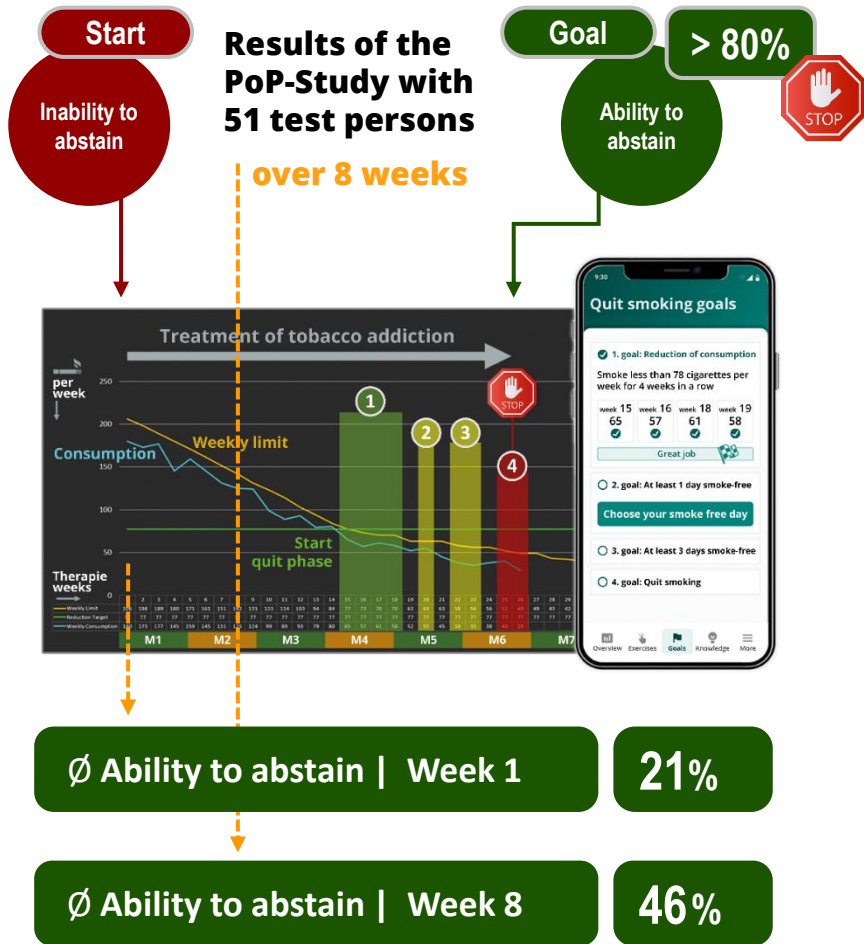
- 4 **Data measurement**
All necessary data are measured via a light barrier when the lid is opened and closed.



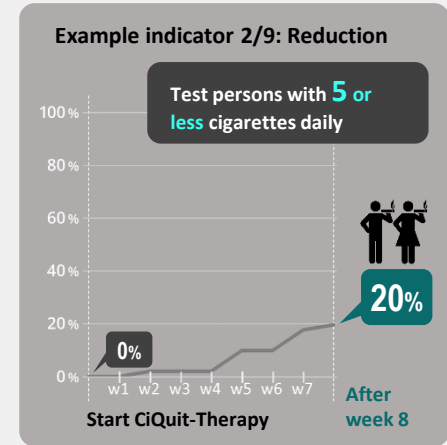
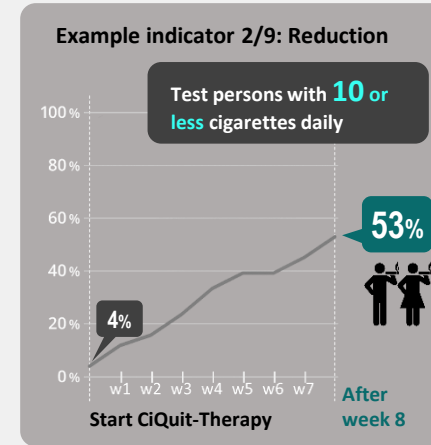
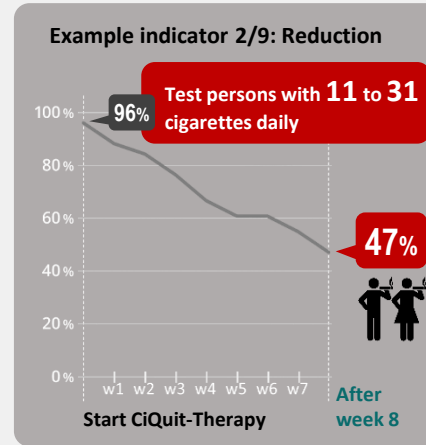
- 5 **Suitable for everyday use**
 - No smoker would enter data into an app or keep a tally for every cigarette over an extended period of time.
 - Should the box be forgotten, smoked cigarettes can alternatively be recorded in the app.

Proof-of-Principle Study (PoP-Study)

The successful study

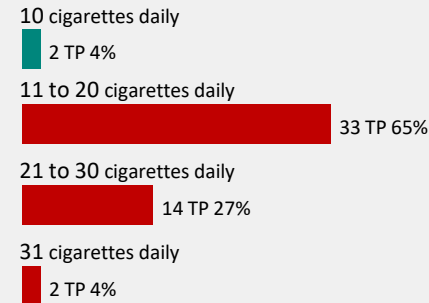


Significant improvements were observed in all 9 indicators of ability to abstain after just 8 weeks!



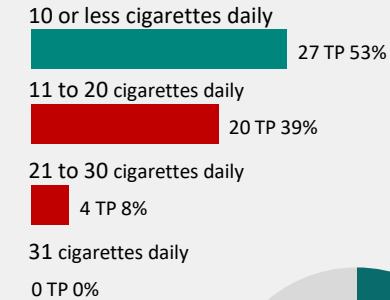
51 test persons (TP)

Start



51 test persons (TP)

Week 8

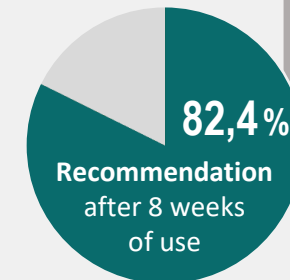


Proof-of-Principle Study

All results at

www.luna-medical.com/en/pop-study/

Example indicator 3/9: Motivation



Primary problem and solution

From reconditioning to abstinence!



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

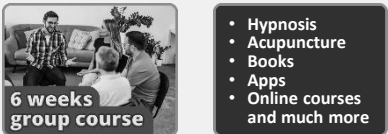
Previous treatment approach

- Medical help



Weaken the effects of nicotine withdrawal

- Psychological help



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 ~~X~~

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. ~~X~~

e.g.: **Nicotine Replacement Therapy**

Key-companies: Johnson & Johnson, GSK, 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>

2. 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

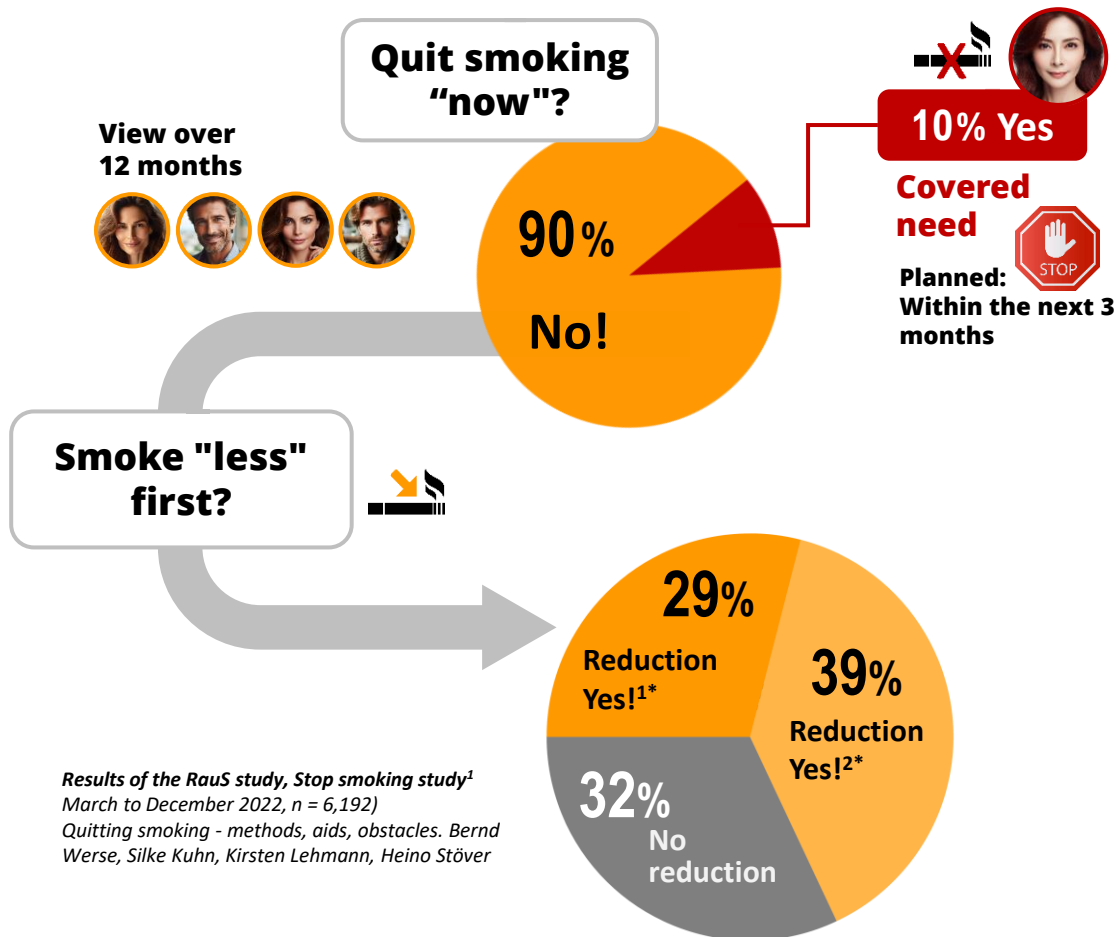
Correct is ...

- "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



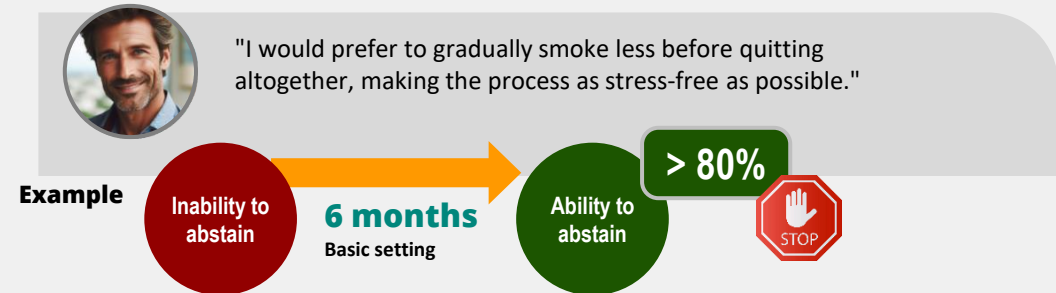
1* 29% = Only smoke on certain occasions

2* 39% = Smoke less cigarettes per day

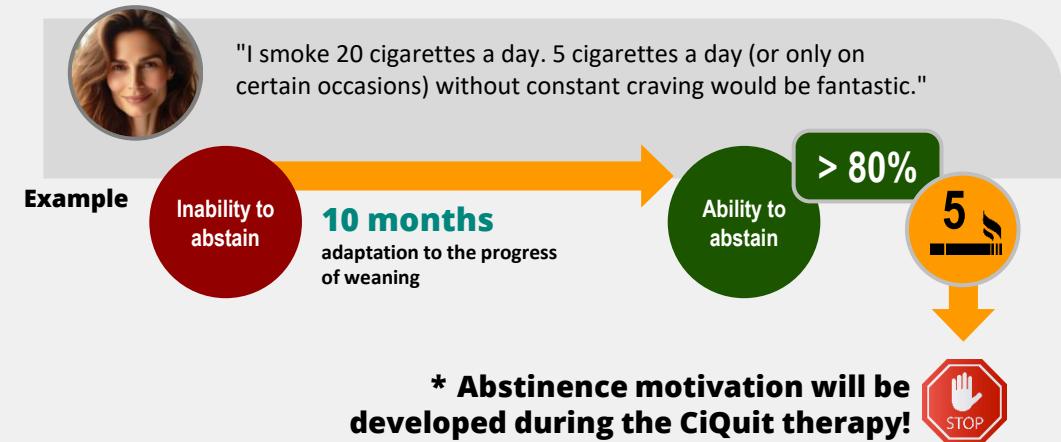


... for the unfulfilled desire

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."

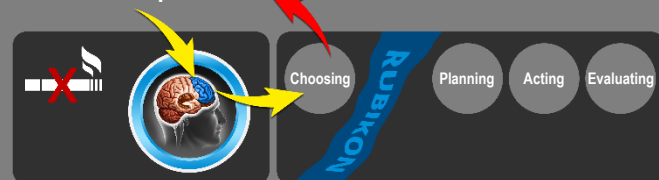
Quit smoking "now"!

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

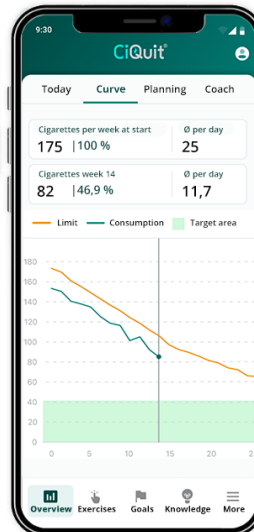
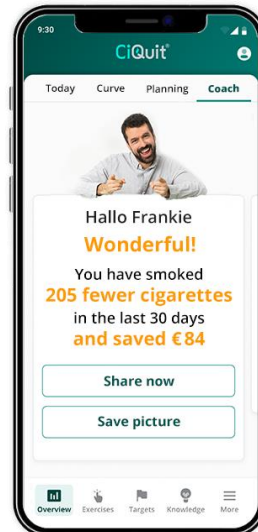
Experience shows that every CiQuit user is immediately approached by other smokers about the **CiQuit-Box**.

Other smokers are asking:

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

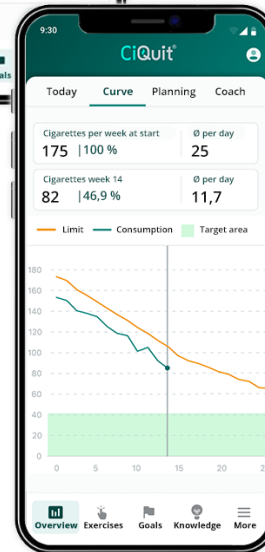
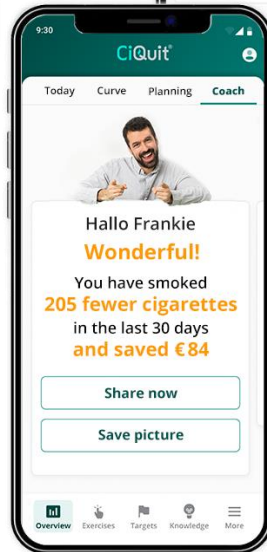
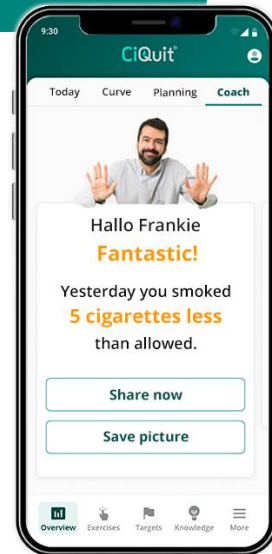


The CiQuit benefit can be communicated very easily via the **CiQuit-App!**



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.

3. Advantages for pharmaceutical companies



Advantages for pharmaceutical companies

3.1 CiQuit and global sales

Smoke "less" first! = Large uncovered need

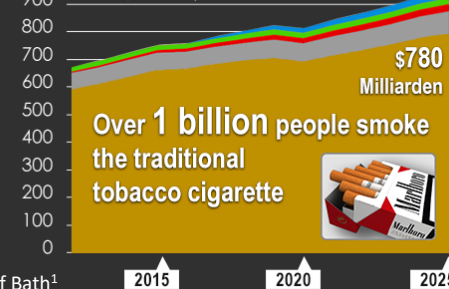
USP:

- No comparable competitor
- 6-fold target group
- Quick decision to use

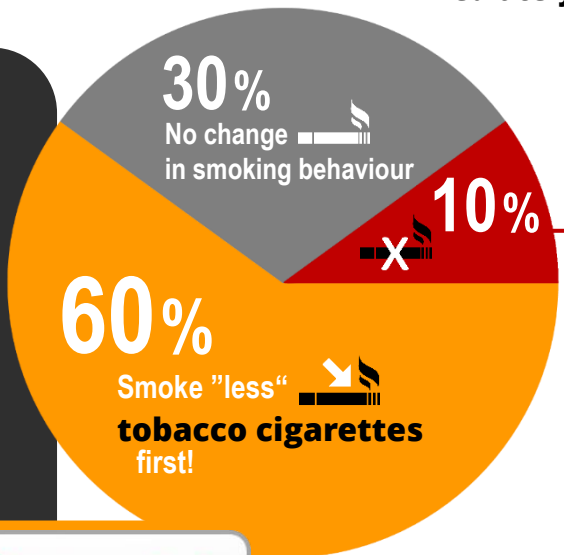
Competitors focus on switching to substitute products or quitting smoking immediately

World Health Organization
Around 1.3 billion tobacco consumers

Global sales of tobacco products in US\$ billion, forecast to 2025



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



High revenue potential

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 billion²

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 billion³

Offers designed to support the desirable complete smoking cessation.

e.g.: Nicotine Replacement Therapy

Key-companies: Johnson & Johnson, GSK, HALEON

Global sales | Forecast 2030
US\$ 3.9 billion⁴

1) Source: <https://www.van-grunstejn.com/sectoranalyse-tabak-resilienz-durch-anpassung>

2) Source: <https://www.verifiedmarketreports.com/product/heated-tobacco-products-https-market-size-and-forecast/>

3) Source: <https://www.verifiedmarketreports.com/product/e-cigarette-and-vaping-market/>

4) Source: <https://www.researchandmarkets.com/reports/4968933/global-smoking-cessation-and-nicotine-de-addiction>

Advantages for pharmaceutical companies

3.2 CiQuit as a therapy supplement

Smoking should be avoided in all disease treatments and therapies to ensure the best possible treatment outcome.

Example: COPD therapy



Examples of pharmaceutical companies with therapies for respiratory diseases



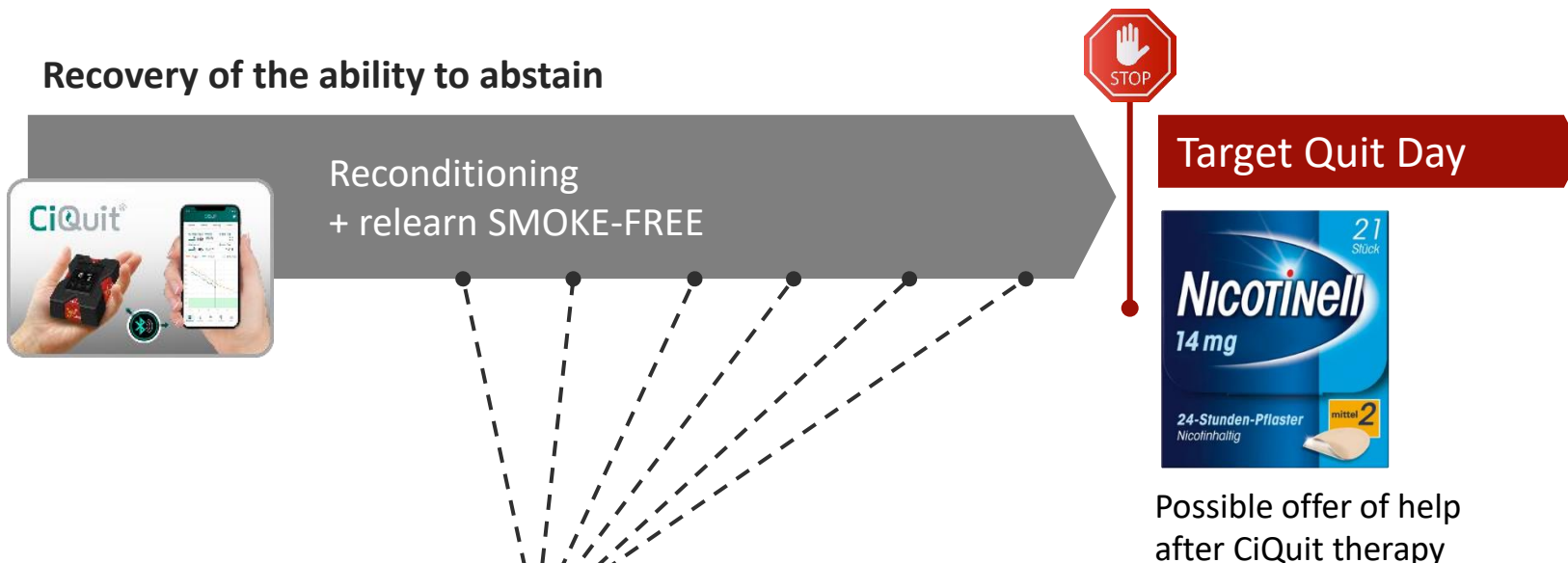
New revenue potential
through
therapy addition

Smoking with existing illness

- Smoking can exacerbate the symptoms of illnesses.
- Smoking can slow down the healing process and impair the effectiveness of medical therapies.
- It is advisable to quit smoking during an illness or therapy to improve chances of recovery and avoid further health complications.

3.3 CiQuit as a combined product - Example: CiQuit + NET

Recovery of the ability to abstain



Selective use during the whole CiQuit therapy



Target Quit Day



Possible offer of help after CiQuit therapy

Current S3 guideline:¹

For smoking reduction

Nicotine replacement therapies + accompanying behavioural therapy = increased probability of successful abstinence

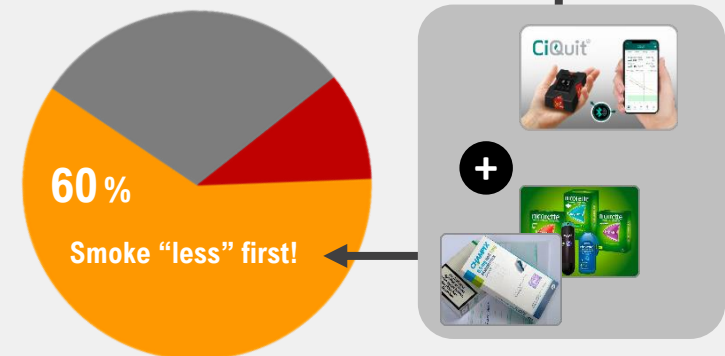
Also for smokers who are not motivated to quit.

New revenue potential through combined products

New target group for pharmaceutical companies

Example Medication		Example NRT	
Champix		Nicorette	
Zyban		Nicotinell	
Asmoken		NICOTIN AL	

Combined therapies



¹) Source : https://register.awmf.org/assets/guidelines/076-006L_S3_Rauchen-_Tabakabhaengigkeit-Screening-Diagnostik-Behandlung_2021-03.pdf

4. The status quo in tobacco cessation

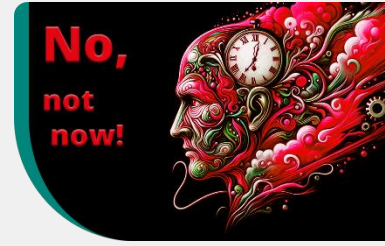
Quit smoking "now"! 

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!**



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.

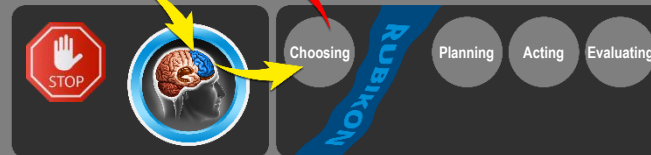


Quit smoking "now"!

Fear of losing something "precious"!

- Long decision-making process
- High persuasion effort

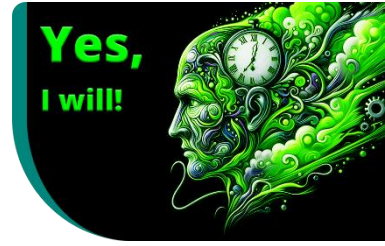
- Fear of loss
 - Fear of failure
 - Failed attempts etc
- The Rubicon **cannot** be crossed



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**



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 %

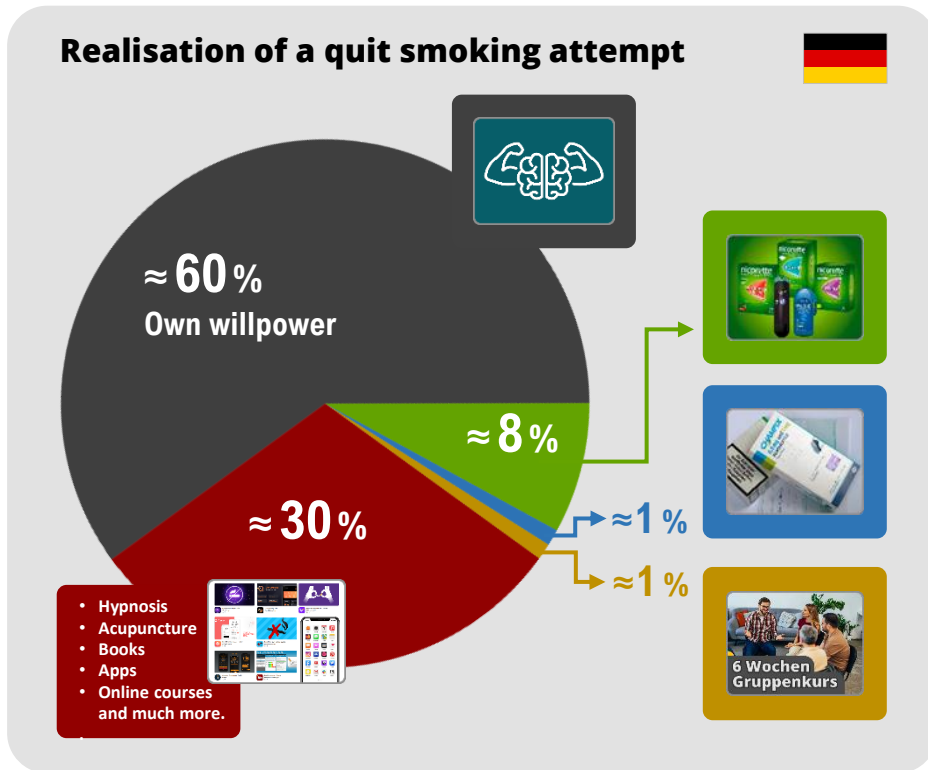
2) Source: https://www.dhs.de/fileadmin/user_upload/pdf/Broschueren/Suchtmedizinische_Reihe_Tabakabha%CC%88ngigkeit_BFREI.pdf
 3) Source: <https://www.aerzteblatt.de/pdf.asp?id=221166> | Trial and failure
 4) Source: https://register.awmf.org/assets/guidelines/076-006I_S3_Rauchen_-_Tabakabhaengigkeit-Screening-Diagnostik-Behandlung_2021-03.pdf
 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/rauchentwoehnung/koennen-nikotinplaster-und-co-bei-der-rauchentwoehnung-helfen>
 8) Source: <https://www.stiftung-gesundheitswissen.de/wissen/rauchentwoehnung/kann-vareniclin-bei-der-rauchentwoehnung-helfen>

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



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



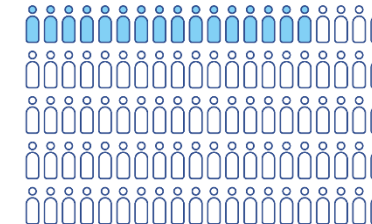
Success rate

≈ 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

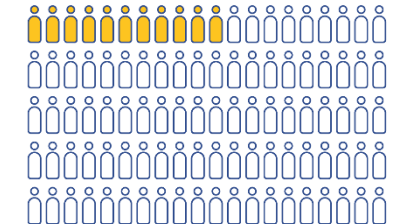


16 out of 100 people who used a nicotine replacement product no longer smoked.*

***(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/rauchentwöhnung/koennen-nikotinplaster-und-co-bei-der-rauchentwöhnung-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	

Goal: Inability to abstain > 80%



Several goals:

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

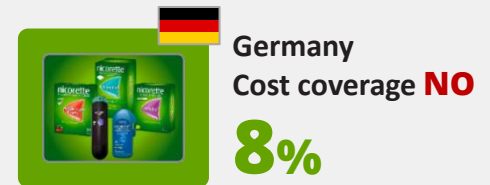
Current S3 guideline¹

“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.”

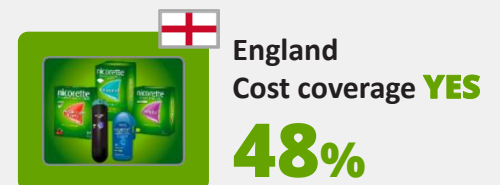
(S3 guideline: p. 97, para. 3, sentence 1)

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

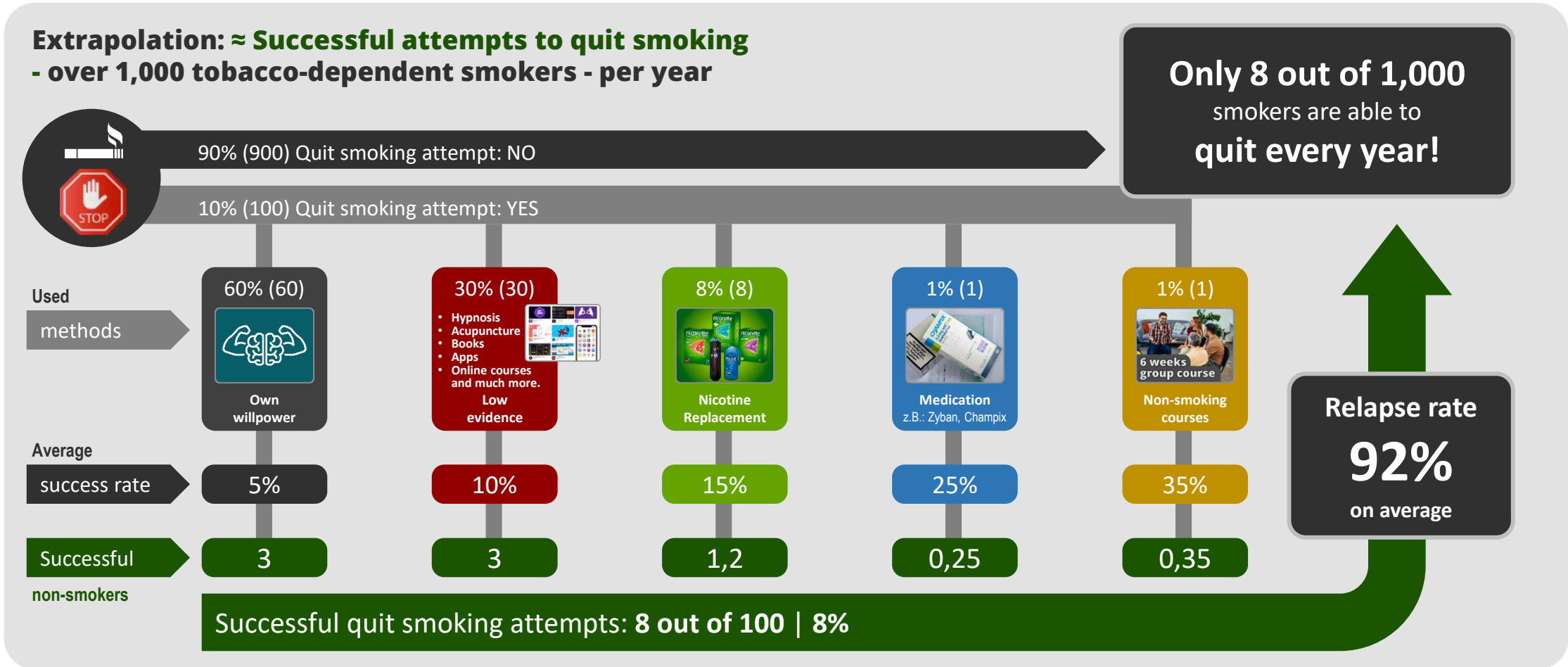
1) Costs may be subsidised by health insurance companies and/or employers

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/Rauchstoppsuche-und-genutzte-Entwöhnungsmethoden>

High relapse rates despite many offers of help

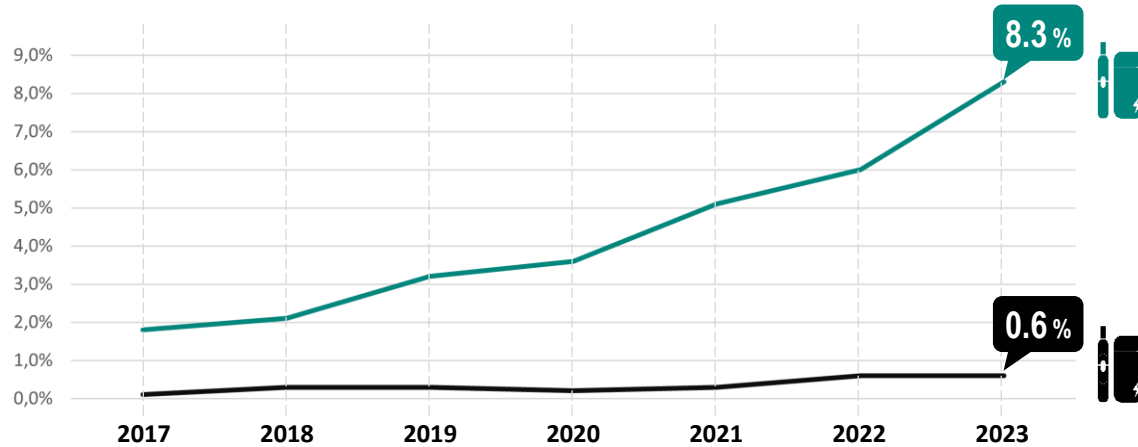
Far too few smokers achieve the leap into permanent abstinence each year.



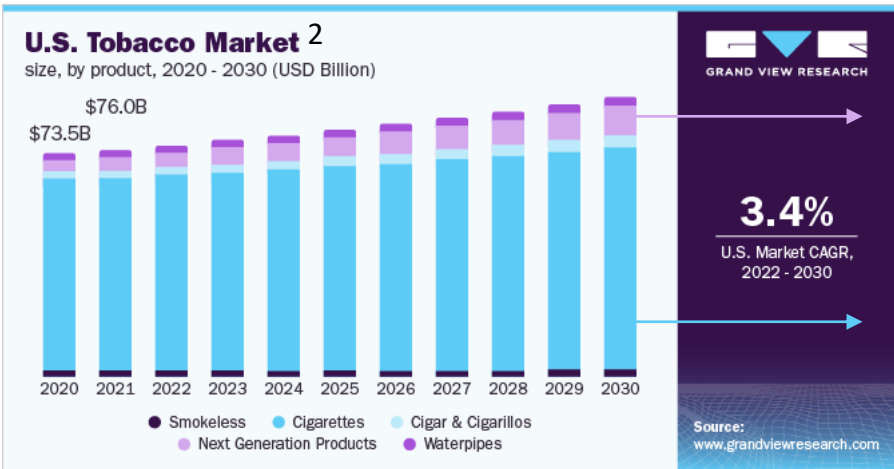
Tobacco heaters (IQOS & Co.) - Germany as an example

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.¹



DEBRA
Deutsche Befragung zum Rauchverhalten
German survey on smoking behaviour



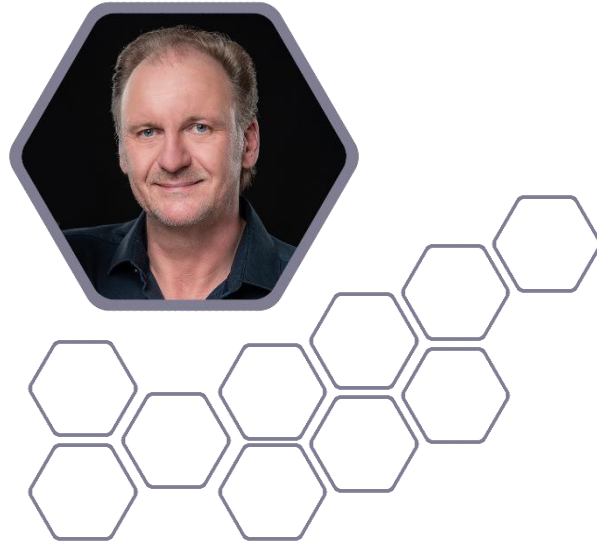
Many smokers return to traditional cigarettes after trying tobacco heaters or e-cigarettes for various reasons:

- 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

Appendix 1: CiQuit and DiGA	33
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CiQuit

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

The scientific background

Detailed information see

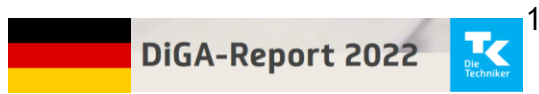
<https://www.luna-medical.com/en/scientific/>



Appendix 1: CiQuit and DiGA

CiQuit becomes DiGA

DiGA = Digital **Health** Application



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.



Ergebnisprotokoll zur Beratung nach § 23 DiGAV

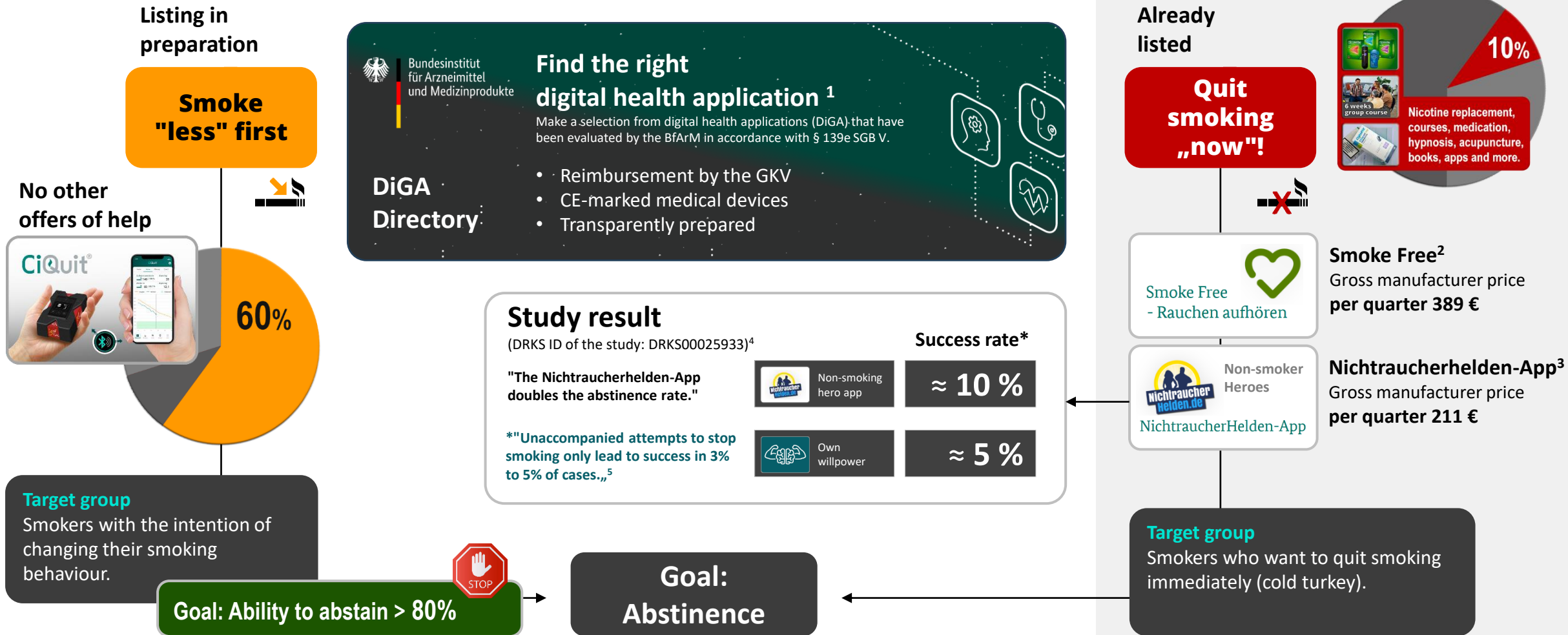
Antragsteller / Applicant	
Institution/Firma/ Affiliation/Company	LUNA medical GmbH
Ansprechpartner/ Contact Name	Andreas Unsicker
Abteilung /Department	CEO
Straße / Street	Yorckstraße 6
Stadt / City	Regensburg
PLZ / ZIP Code	93049
Land / Country	Deutschland
Telefon / Phone	+49 172 533 42 92
E-Mail / email	unsicker@au-innovation.com
Angaben zur Beratung / Information on advice	
Verfahrensnummer/ Procedure number	2022-100
Produktname/ product name	CiQuit
Teilnehmende BfArM / Participants BfArM	- Anna Nickel, Gesprächsleitung Innovationsbüro - Dr. Michael Bühlen, klinischer Assessor - Dr. Tobias Möllers , DiGA Assessor - Florian Strauch, DiGA Assessor
Ihre Teilnehmenden/ Your participants	- Andreas Unsicker, LUNA medical GmbH - Prof. Dr. Anil Batra, Universität Tübingen - Dr. Eva Hoch, IFT - Dr. Larissa Schwarzkopf, IFT - Pierre Jäger, Johner Medical - Till Gladow, dmac - Cordula Forster, dmac - Laura Brandt, dmac

Ihre Fragestellungen / Your questions	Position und Antwort des BfArM/ Position and response of BfArM
Frage 1: Stimmt das BfArM der vorgeschlagenen Studiensynopse bezüglich des mN „Verbesserung des Gesundheitszustands“ grundsätzlich zu?	Ja, das BfArM stimmt grundsätzlich der vorgeschlagenen Studiensynopse zu. Folgende Aspekte werden als positiv bewertet: 1. Standardisierte ärztliche Kurzintervention für 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 Rauchstoptages.
Frage 2: Zum Nachweis der Verbesserung des Gesundheitszustands dient der Endpunkt der 7-Tage-Punktprävalenz, validiert über Cotinin-Messung. Als klinisch relevanter und für den Nachweis ausreichender Effekt wird ein signifikanter Unterschied der Abstinenzrate zwischen Interventions- und Kontrollgruppe	Ja, das BfArM stimmt zu, dass ein signifikanter Unterschied der Abstinenzrate zwischen Interventions- und Kontrollgruppe, unabhängig von der absoluten Abstinenzrate der Interventionsgruppe ausreichend für einen klinischen relevanten Effekt ist.

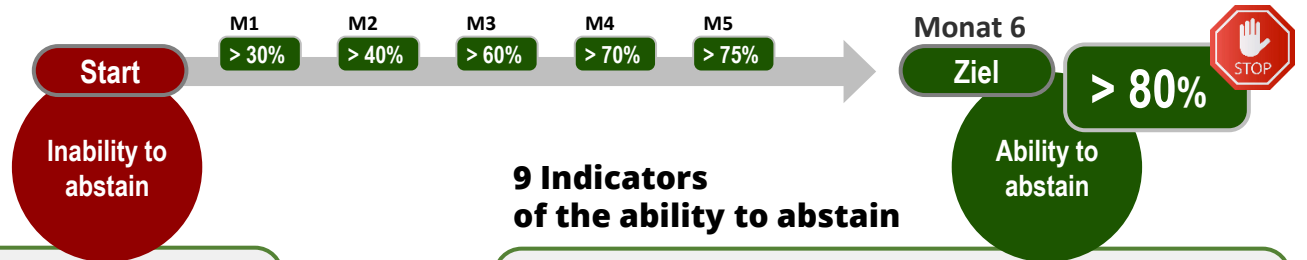
1) Source: <https://www.tk.de/resource/blob/21125136/b17480b9336ea42df83b5b6b213a0f88/tk-diga-report-2022-data.pdf>

Appendix 2: CiQuit and the DiGA directory

Tobacco cessation in the DiGA directory Germany



Appendix 3: The 9 key indicators



9 Indicators of the inability to abstain

1. First cigarette immediately or shortly after waking up
2. More than 10 cigarettes a day

9 Indicators of the 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

Primarily physical (bodily) dependence

Primarily psychological (mental) dependence

3. No motivation to try to quit smoking
4. Inability to control the smoke impulse
5. No awareness of one's own smoking behaviour
6. Strong link between trigger stimuli and cigarette (classical conditioning)
7. Ambivalent attitude towards cigarettes (e.g.: smoking is harmful, but helps in stressful situations)
8. Strong craving when trying to reduce
9. Significant discomfort about quitting smoking (fear of failure, fear of loss)

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)**

Primary goals:

1. Suitable for everyday use for the majority of smokers
2. The restoration of the ability to abstain
3. Building motivation to quit smoking



Common mental attitude:

Fear of losing something "precious"!

Change mental attitude:

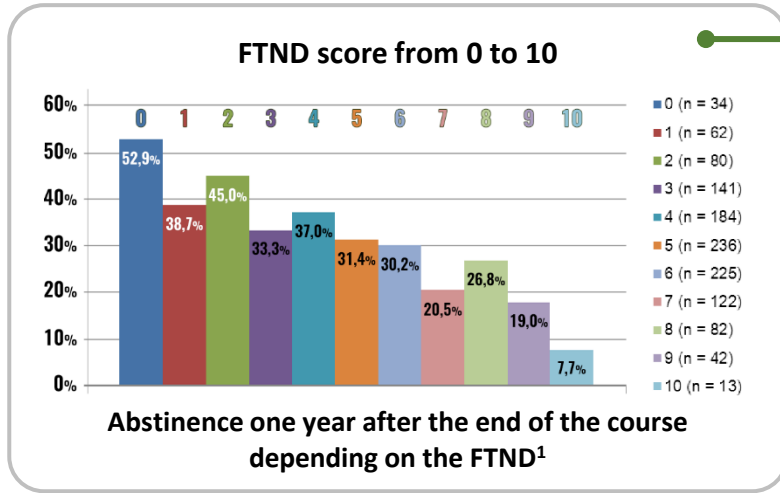
Building "anticipation" for a smoke-free life!

Appendix 4: 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 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*

Goal



Ability to abstain



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.

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"!



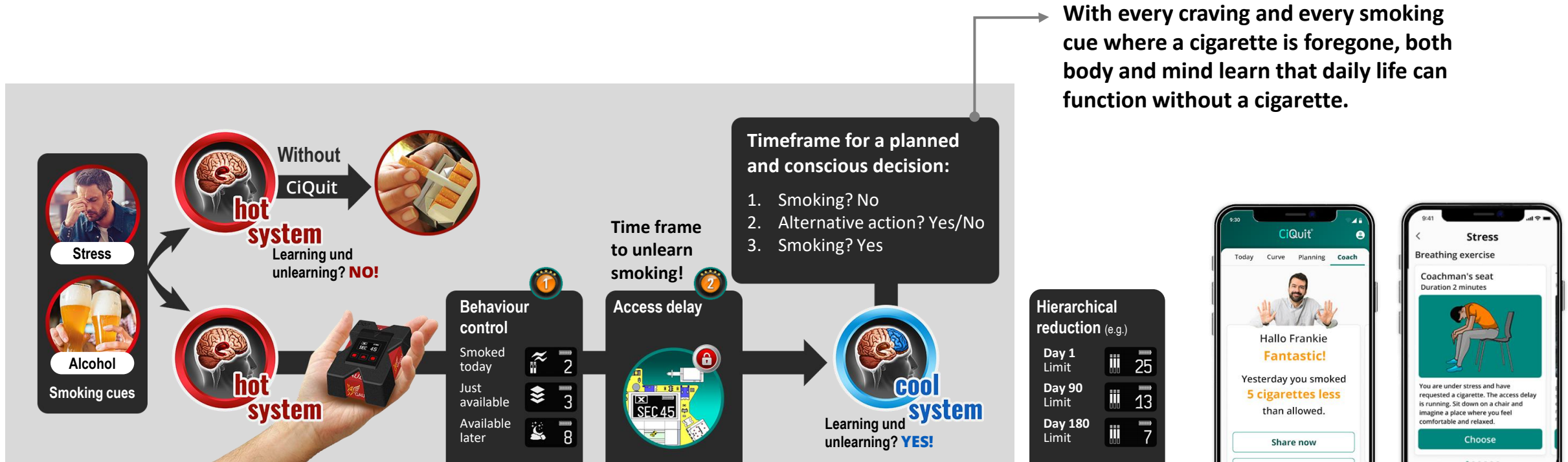
Learning and unlearning **"delete!"** can only be implemented in the "cool system"!



- 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.

Examples:

Day 1
20 seconds

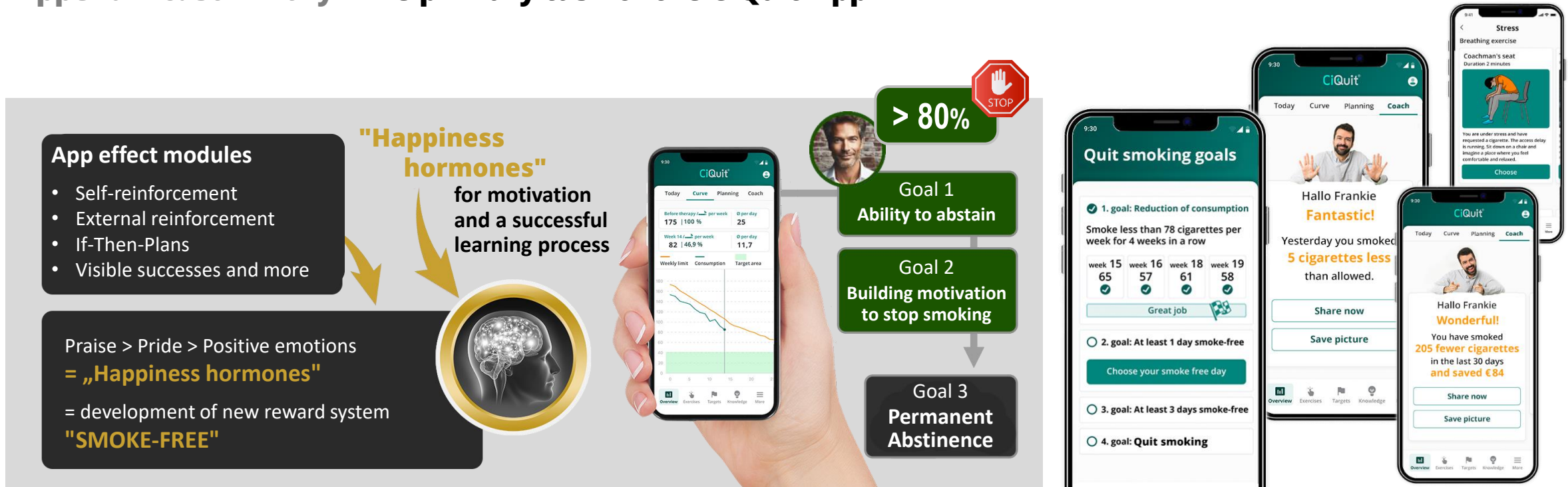
Day 39
1:17 minutes

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.
- 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.

Appendix 6: 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."