



The Scientific Background



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Tobacco consumption

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



Further PDF documents

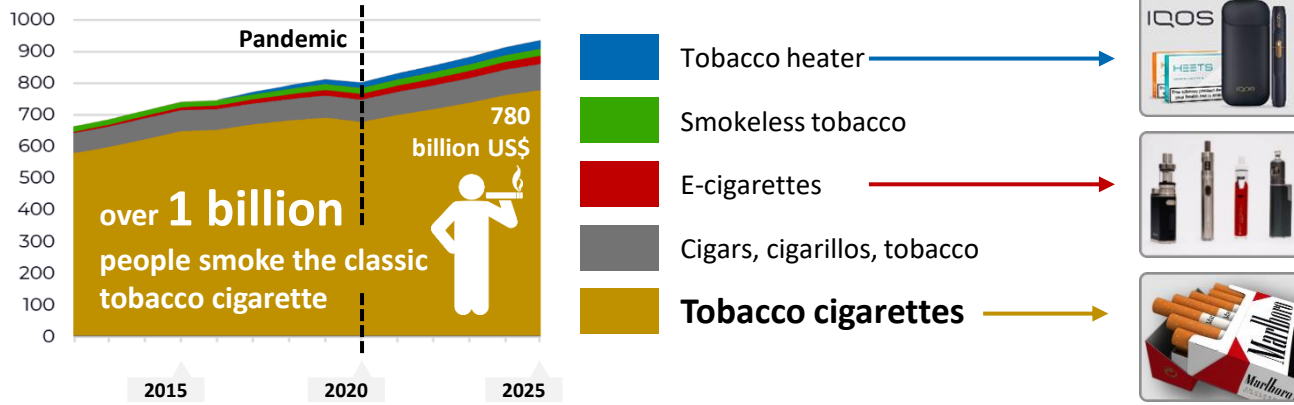
- **The scientific background**
<https://www.luna-medical.com/en/scientific/>
- **The proof-of-principle study**
<https://www.luna-medical.com/en/pop-study/>
- **The patent**
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- **Cooperations with pharmaceutical companies**
<https://www.luna-medical.com/en/pharmaceuticals/>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



World Health Organization

Worldwide 1.3 billion tobacco consumers

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



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



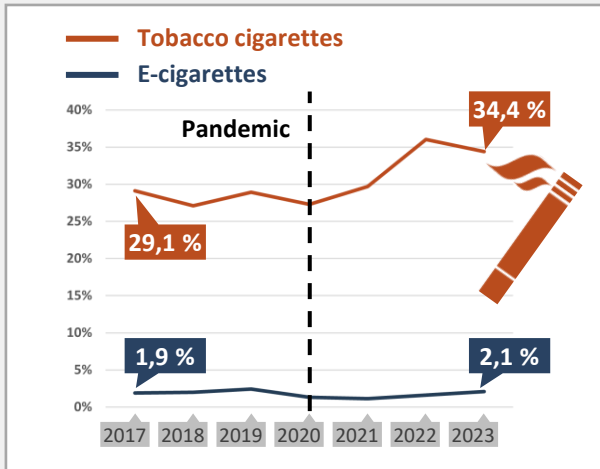
Every year, an estimated **4.5 trillion** cigarette butts with more than 7,000 toxic chemicals end up in the environment.^{4,5,6}

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>

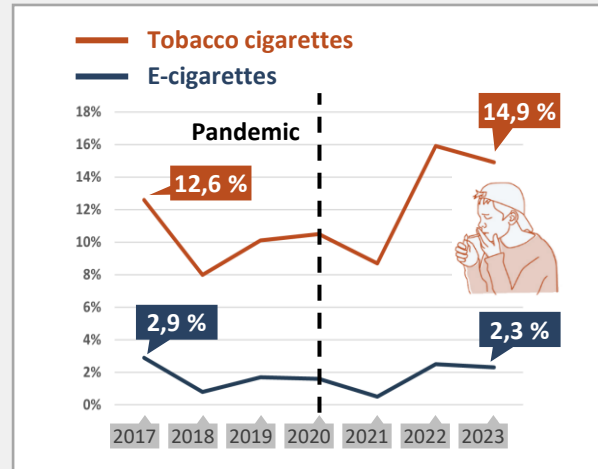
4) Source: <https://www.nabu.de/natur-und-landschaft/aktionen-und-projekte/meere-ohne-plastik/29901.html>
 5) Source: <https://www.euwid-recycling.de/news/wirtschaft/jaehrlich-werden-45-billionen-zigarettenstummel-weggeworfen-170522/>
 6) Source: https://www.euwid-recycling.de/fileadmin/data/euwid_recycling_und_entsorgung/news/images/Talking_Trash_EN.pdf

Foreword | The Development of Smoking Germany as an example

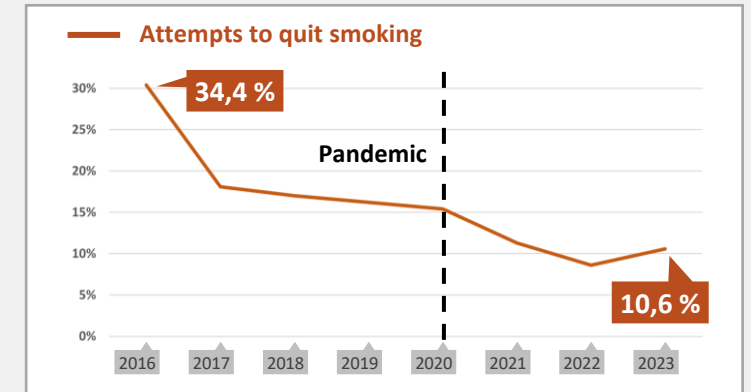
Since the pandemic, the number of people smoking tobacco cigarettes has skyrocketed.



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	
Measurement time	Population 14 years + 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

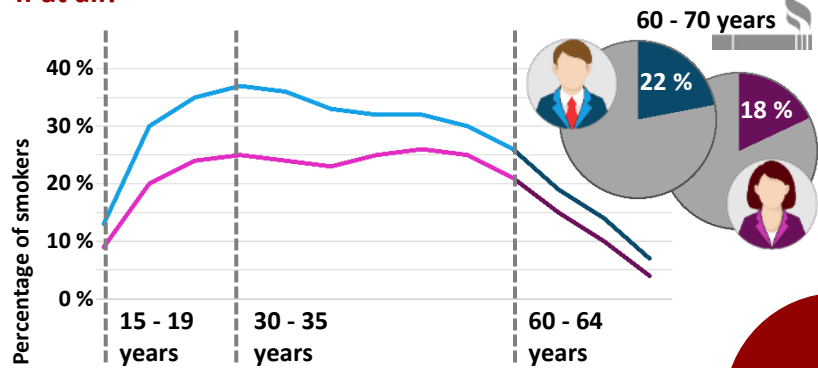
"In the healthcare system, we finally must pull together in order to bring comprehensive help to quit smoking, onto the streets."³

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-vo>

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



Current S3 guideline¹

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

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

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

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

Inability to abstain



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

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



Prof. Dr. Anil Batra

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

Stephan Mühlig
Head of the Psychotherapeutic University Outpatient Clinic TU Chemnitz



Prof. Dr. Stephan Mühlig

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

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



Prof. Dr. Ute Mons

1) Source: https://register.awmf.org/assets/guidelines/076-006l_S3_Rauchen_Tabakabhaengigkeit-Screening-Diagnostik-Behandlung_2021-03.pdf

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

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

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

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 **Rubicon model**: page 19 and page 29

*see Worth knowing - Appendix 3: Tobacco heaters (IQOS & Co.) - Germany as an example

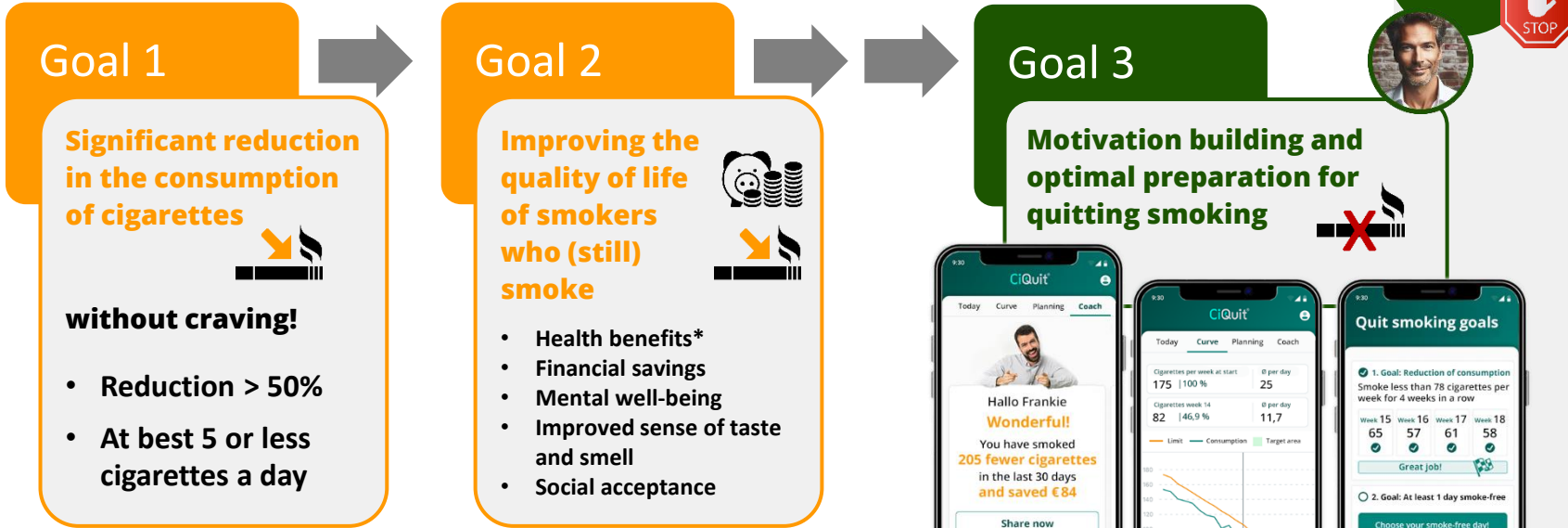
**see Worth knowing - Appendix 2: Success rates in tobacco cessation

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

The solution

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

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



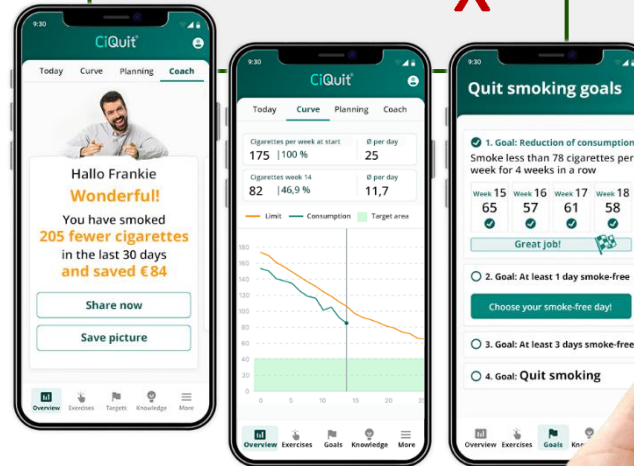
What addiction experts say!

"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.



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



CiQuit®
Reconditioning



**For a detailed explanation see:
2. The effectiveness of CiQuit**

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

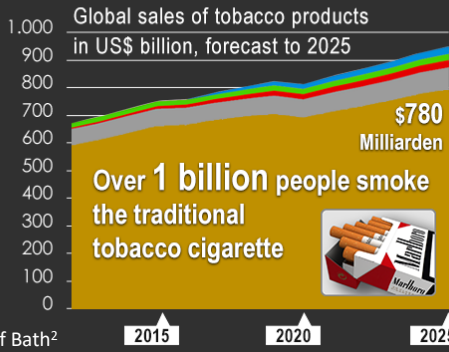
That's what science says!

"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 = [Tobacco heater icon] + [E-cigarette icon] + [Nicotine Replacement Therapy icon]

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>

1. Scientific background to the CiQuit application



1.1 The problem 1/8

Psychological dependence

Classical conditioning



The process of smoking is deeply intertwined with individual triggers. These triggers can come from situations, emotions or certain places.

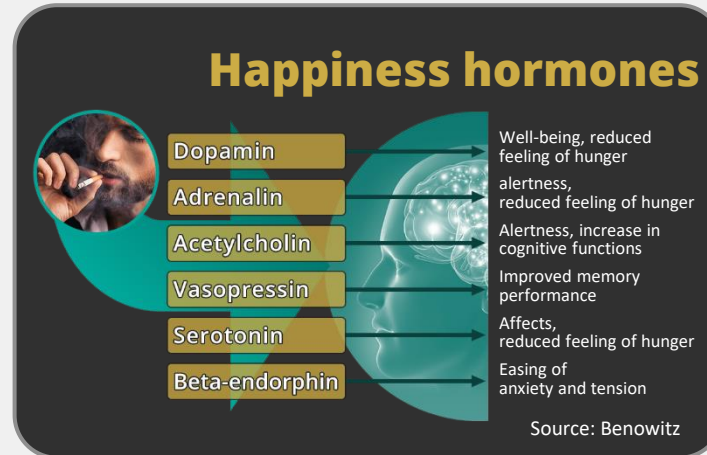
These triggers condition smokers and trigger the craving for a cigarette automatically and subconsciously.

Detailed explanations:

Psychological dependence: See Appendix 7

Psychological dependence

Classical conditioning



Smoking stimulates the reward centre, which leads to the release of "happiness hormones".

This hormone release creates a sense of well-being and makes smoking a pleasant experience.

At the same time, this process leads to a strong dependency that makes it difficult or even impossible to quit smoking.

Physical dependence

Nicotine receptors

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



Source: Henningfield

"Cigarettes stimulate the formation of new receptors in the brain where nicotine docks. And more receptors demand more cigarettes - a vicious circle."¹

Dr. Michael Heidler,
Graduate psychologist and head of
the Institute for Tobacco Cessation

Detailed explanations:

Physical dependence: See Appendix 6

1) Source: <https://www.aachener-zeitung.de/leben/gesundheit/junkie-stoff-zigarette-nikotin-hat-ein-gro%C3%9Feres-suchtpotenzial-als-heroin/2998103.html>

Psychological (mental) dependence + Physical (bodily) dependence

Smoking cues

Stress Food Alcohol Driving a car

Happiness hormones

Dopamin	Well-being, reduced feeling of hunger
Adrenalin	Alertness, increase in cognitive functions
Acetylcholin	Improved memory performance
Vasopressin	Affects, reduced feeling of hunger
Serotonin	Easing of anxiety and tension
Beta-endorphin	

Source: Benowitz

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

Source: Henningfield



The smoking process takes place in regions of the brain that are beyond the reach of free will.

Access "Free will":
No!



- Subconscious actions
- Reward centre
- Addiction centre

Access "Free will":
Yes!



- Planned decisions
- Learning and unlearning
- Reconditioning

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

The "hot system" is impulsive and reacts automatically and subconsciously. In cigarette smoking, the "hot system" is activated by the anticipation (prelude) of the immediate pleasure and relaxation that nicotine provides. It responds to cravings, but also to stress, boredom, and many other stimuli that trigger the reach for a cigarette.

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

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

If the **"cold system"** could be activated with every reach for a cigarette, it could counteract the smoking impulse that comes from the **"hot system"**.



**The brain has learned:
Smoking is a blissful affair!**

Psychological (mental)
dependence +
Physical (bodily)
dependence

Smoking cues

Stress Food Alcohol Driving a car

Happiness hormones

Dopamin	Well-being, reduced feeling of hunger
Adrenalin	Alertness, increased feeling of hunger
Acetylcholin	Alertness, increase in cognitive functions
Vasopressin	Improved memory performance
Serotonin	Affects, reduced feeling of hunger
Beta-endorphin	Easing of anxiety and tension

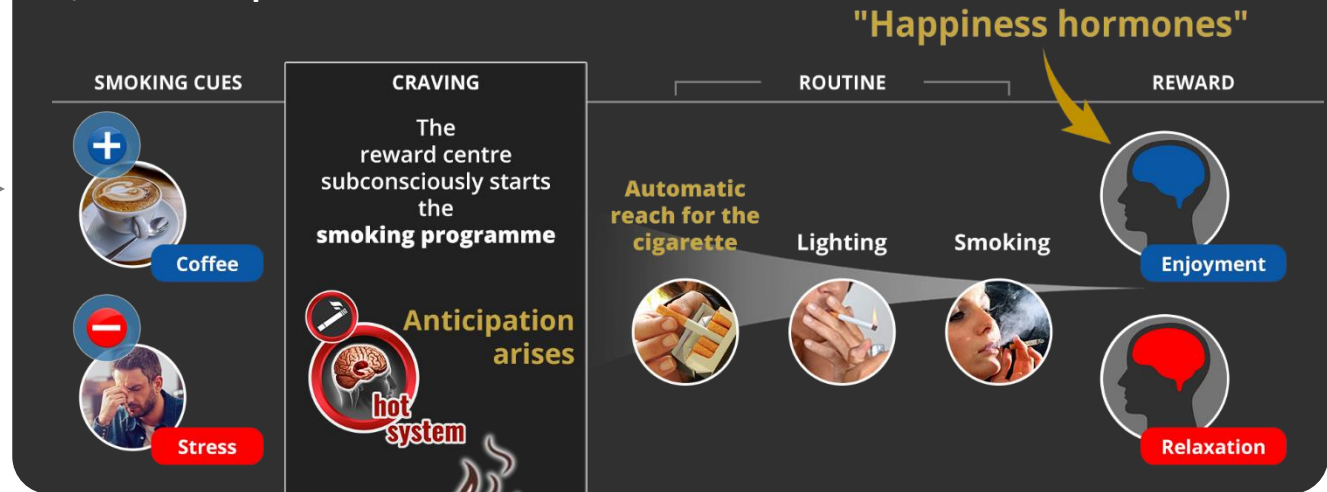
Source: Benowitz

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

Source: Henningfield

Conditioning in the reward centre through 1,000-fold repetition:



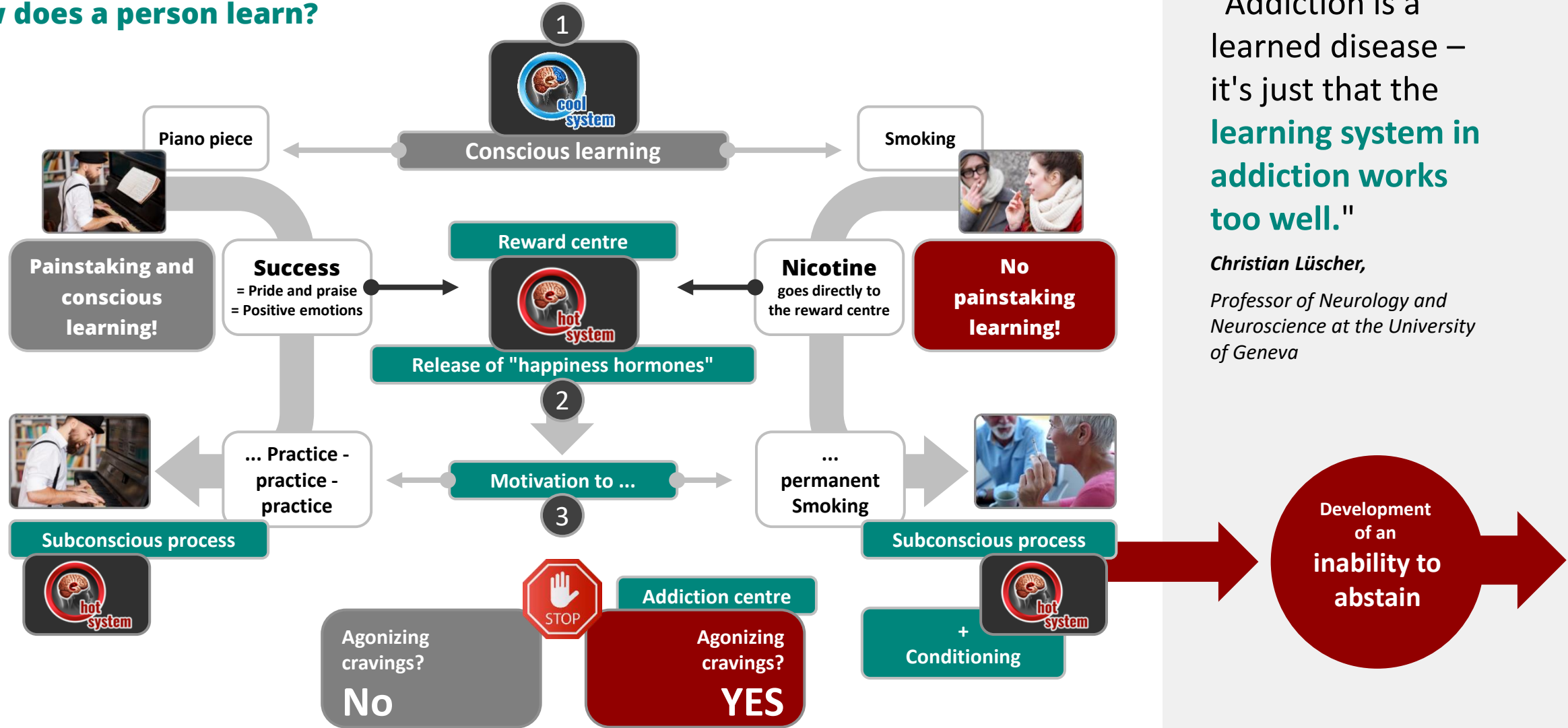
The smell of coffee ...



... triggers the automatic reach for a cigarette!

Excursus: Learning system

How does a person learn?



"Addiction is a learned disease – it's just that the learning system in addiction works too well."

*Christian Lüscher,
Professor of Neurology and Neuroscience at the University of Geneva*

Problem 1 | Part 1/2

The inability to abstain prevents successful smoking cessation!



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

Quit smoking attempt - method and success rate:

Only willpower

≈ 5 %

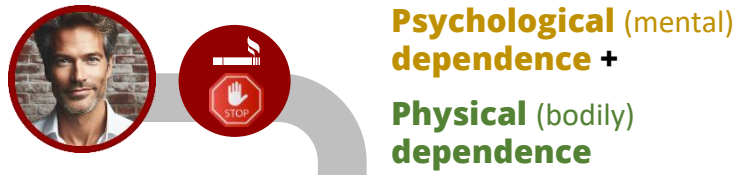
With a firm resolution to quit smoking for good and never light up a cigarette again, the probability of abstinence is 25% one week after making the resolution and less than 5% six months later.¹ Unaccompanied attempts to stop smoking only lead to success in 3% to 5% of cases.²

Nicotine Replacement Therapy

≈ 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

Further methods and success rates:
See Appendix 1 to 3



Addiction centre

Effects of nicotine withdrawal “Hungry nicotine receptors”

- Agonizing craving
- Irritability and restlessness
- Frustration and anger
- Anxiety
- Sleep disorders
- Concentration disorders
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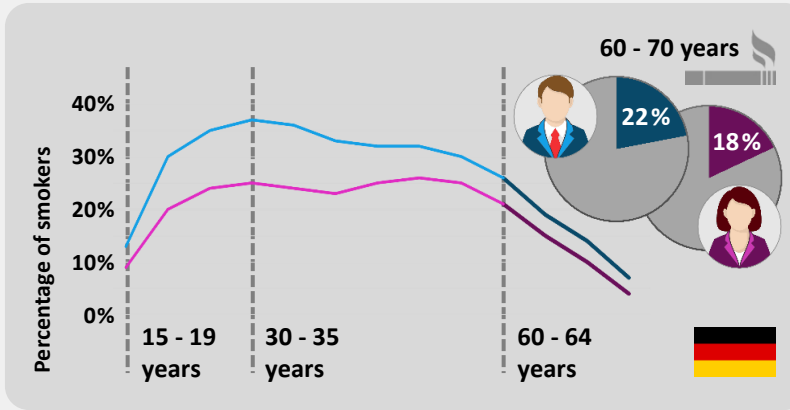


Quelle: J. Henningfield

High level of suffering

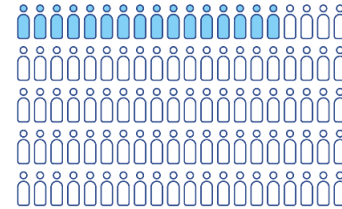
High relapse rates (despite help)

Next attempt to quit smoking is usually postponed for years



Do nicotine replacement products help to quit smoking?³

Nicotine replacement products



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

*(After 6 or 12 months)

Placebo product



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

Quelle: Hartmann-Boyce et al. (2018)



1) Source: https://www.dhs.de/fileadmin/user_upload/pdf/Broschueren/Suchtmedizinische_Reihe_Tabakabha%CC%88ngigkeit_BFREI.pdf
2) Source: <https://www.aerzteblatt.de/pdf.asp?id=221166> | Versuch und Scheitern

3) Source: <https://www.stiftung-gesundheitswissen.de/wissen/rauchentwoehnung/koennen-nikotinplaster-und-co-bei-der-rauchentwoehnung-helfen>
4) Source: <https://www.cochrane.de/news/ein-neuer-cochrane-review-untersucht-die-wirksamkeit-von-verschiedlichen>

Problem 1 | Part 2/2

The inability to abstain prevents successful smoking cessation!



The 9 key indicators of the inability to abstain

Primarily physical (bodily) dependence

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

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)

- The indicators are responsible for the inability to abstain by addressing both the physical and mental dependence.
- The indicators build on each other and reinforce one another.
- The stronger the individual indicators are, the more difficult it is to achieve lasting abstinence.

Common mental attitude:

Fear of losing something "precious"!



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

Problem 2 | Part 1/2

The inability to abstain already hinders the **motivation** to attempt quitting smoking!

People who are addicted to tobacco often exhibit the following thoughts and attitudes:

If I quit smoking,

- I'll just be a nervous wreck.
- I'll become aggressive and unbearable.
- I probably won't succeed anyway and then I'll feel like a failure.
- My work will suffer.
- My suffering will be great and long-lasting.
- I will gain weight.
- At best, I'll become an anti-pleasure, uncomfortable, boring, and militant non-smoker.

9 Indicators of the inability to abstain

Inability to abstain

Primarily physical (bodily) dependence

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

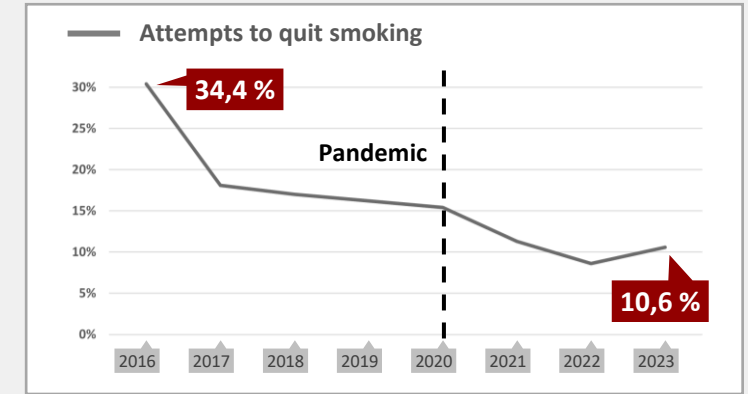
Primarily psychological (mental) dependence

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)**

Common mental attitude:

Fear of losing something "precious"!

For years, the number of smokers who make at least one serious **attempt to quit smoking has been declining.**¹



"Studies show that two out of three smoking patients in general practices are in the stage of precontemplation or contemplation and one out of four is in the stage of preparation.

Only about 1 out of 14 is in the stage of preparing for smoking cessation.²

Problem 2 | Part 2/2

The inability to abstain already hinders the **motivation** to attempt quitting smoking!

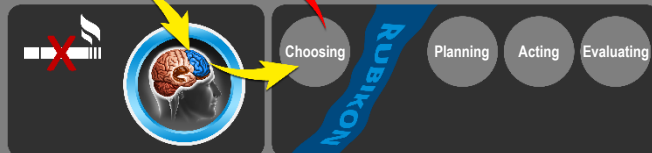
Quit smoking "now"!

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!

Explanation in the context of the Rubicon model

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."

Motivational psychology

Rubicon model²

- 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

The decision-making process (choosing) of quitting smoking can take years, and possibly decades, for tobacco-dependent smokers. Those affected are not willing or able to cross the "Rubicon" in their current life situation.

= No, not now!

• Planning

Planning a smoking cessation attempt is not being considered now or at this time.

• Acting/Evaluating


Therefore, the subsequent actions of **ACTING** and **EVALUATING** do not even come into play.

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

1.2 The solution 1/8

Three fundamental conditions for successful smoking cessation are:

- 1. Quick decision-making for behaviour change**
- 2. Motivation to try to quit smoking**
- 3. High level of ability to abstain**



The power of tobacco addiction:

“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 !!!

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.”¹**

Prof. Dr. Anil Batra

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

... Reconditioning



- 1 Behavior change**
- 2 Motivation**
- 3 Ability to abstain**

Detailed explanation under:

2. The effectiveness of CiQuit

1.2 The solution 2/8

Three key elements for problem solving



Reconditioning

1 Reduction = quick decision to **change behaviour**

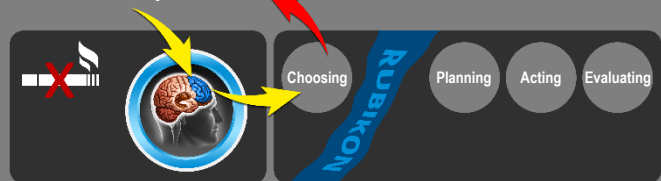
Quit smoking "now"!

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!

"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,*

Motivational psychology

Rubicon model

- **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.

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

Three key elements for problem solving



Reconditioning

2 Building, reinforcing and manifesting the **motivation** to try to quit smoking

Goals

The motivation or "Yes, I will!" quitting smoking, as a prerequisite for abstinence, is strengthened and manifested during the process of the CiQuit therapy.

In addition to physical preparation, three mental components are trained and consolidated during the therapy:

- **Confirmed self-awareness,** that individual smoking situations can also be mastered without a cigarette.
- **Self-confidence,** that you don't have to do without something "valuable" for the rest of your life.
- **Self-confidence,** that being smoke-free means a gain in quality of life.



1.2 The solution 4/8

Three key elements for problem solving



Reconditioning

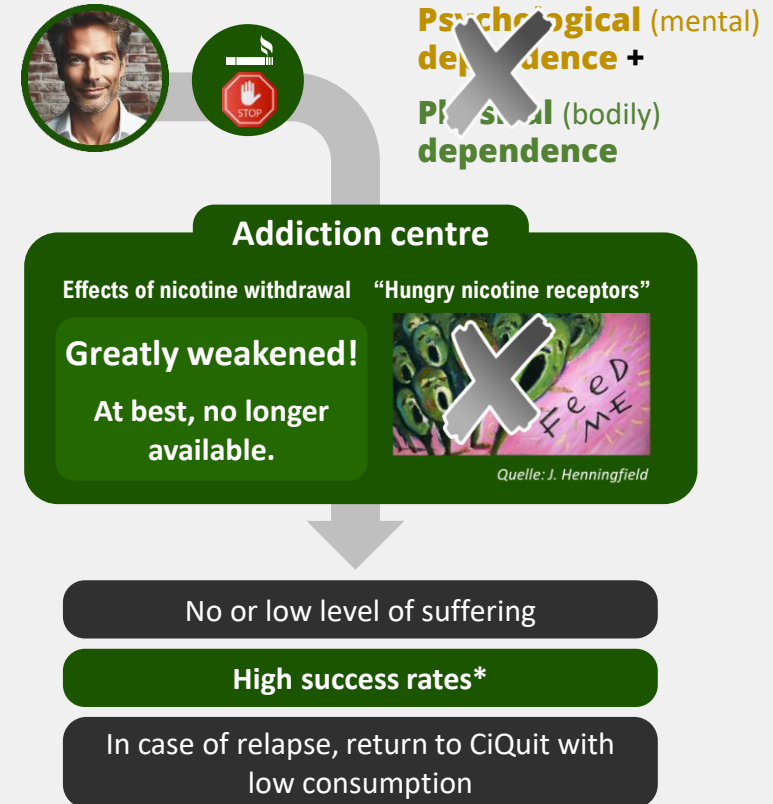
3 Restoring the ability to abstain

- At CiQuit, the **restoration of ability to abstain** aims to prepare both body and mind for quitting smoking by gradually reducing dependence on cigarettes, both physically and psychologically.
- The result of this comprehensive preparation with CiQuit is that, after quitting, craving for addiction and withdrawal symptoms are either weak or, at best, no longer present, which inevitably makes quitting smoking much easier.
- The partial successes achieved through CiQuit - significant reduction in the number of cigarettes without craving and the enhancement of quality of life - also strengthen self-confidence and mental determination to realize a smoke-free life.

The ability to abstain

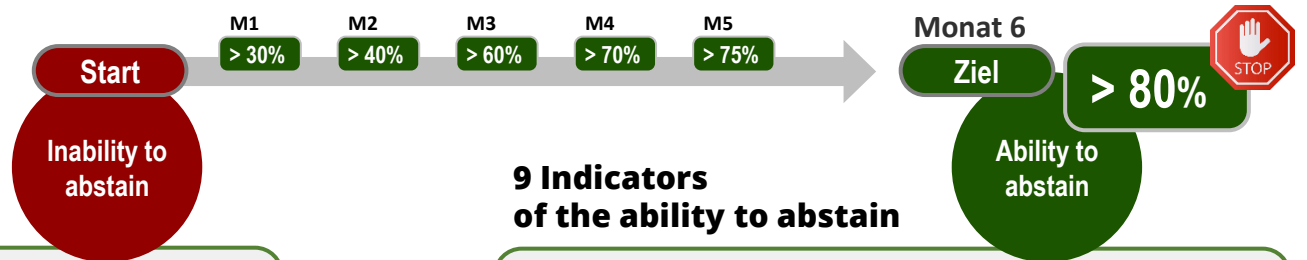
- **motivates** the attempt to quit smoking
- **enables** successful smoking cessation

Ability to abstain



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

9 key indicators



9 Indicators of the inability to abstain

Primarily physical (bodily) dependence

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

9 Indicators of the ability to abstain

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 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"!

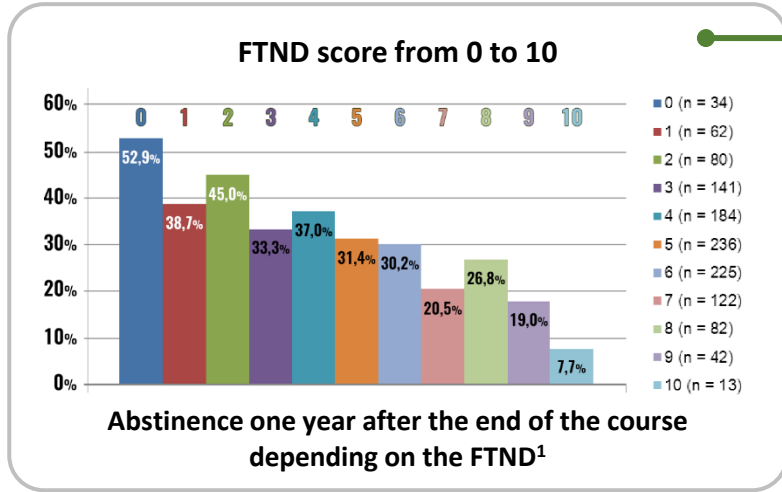
Change mental attitude:

Building "anticipation" for a smoke-free life!

The scientific derivation - CiQuit in the context of the Fagerstrom Test (FTND)*

CiQuit® Goals

Ability to abstain > 80% 



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

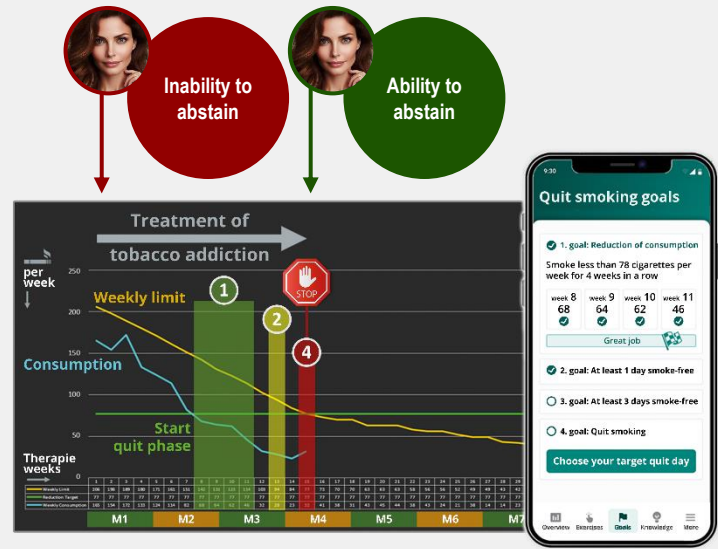
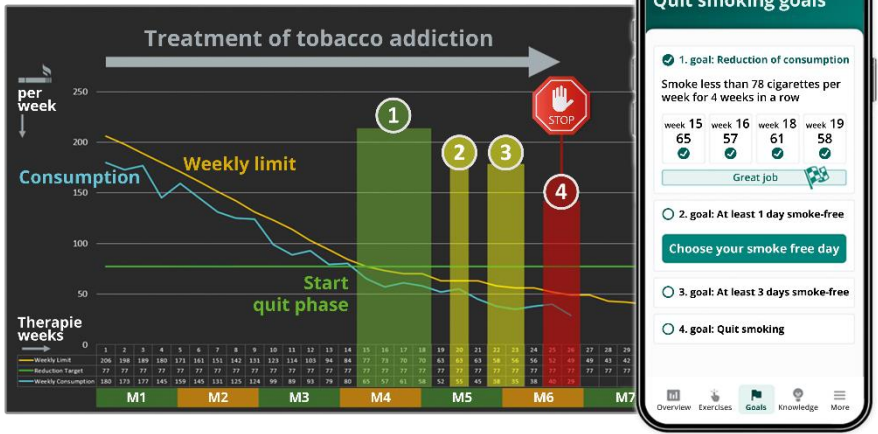
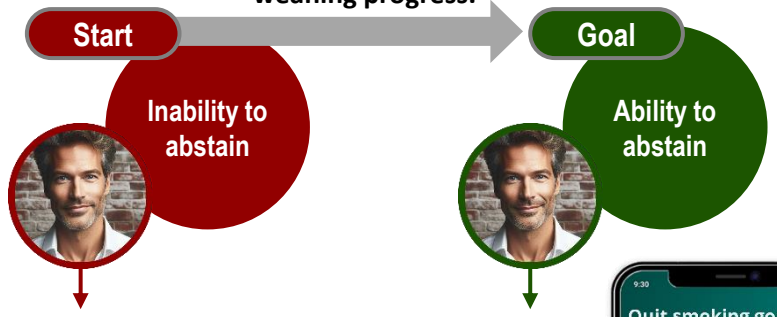
Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in the cinema)? (1) Yes (0) No

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

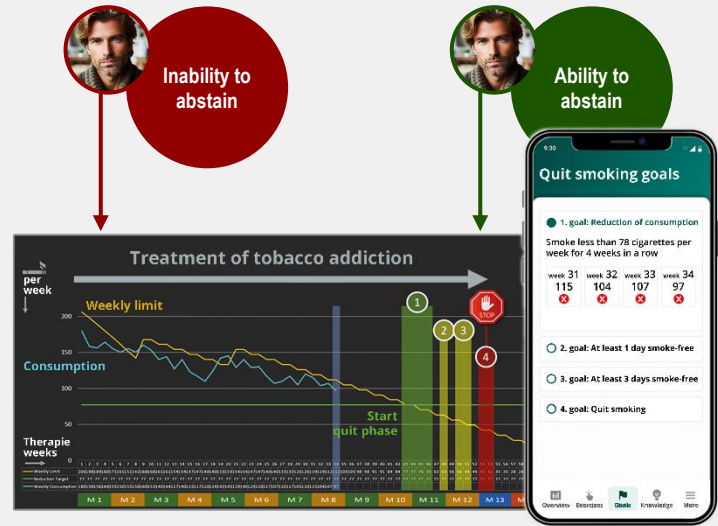
1) Source: https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/5_Publikationen/Drogen_und_Sucht/Berichte/Projektbericht_Effektivitaet_von_Tabakentwöhnung_in_Deutschland.pdf | p. 59
 2) Source: https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/5_Publikationen/Drogen_und_Sucht/Berichte/Projektbericht_Effektivitaet_von_Tabakentwöhnung_in_Deuts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

CiQuit therapy adapts to the individual abilities of the user.

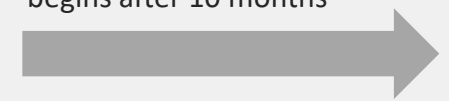
6 month (Basic setting)
Or adaptation to the weaning progress.



Underload
Smoking cessation is brought forward e.g.: Target Quit Day after 3.5 months

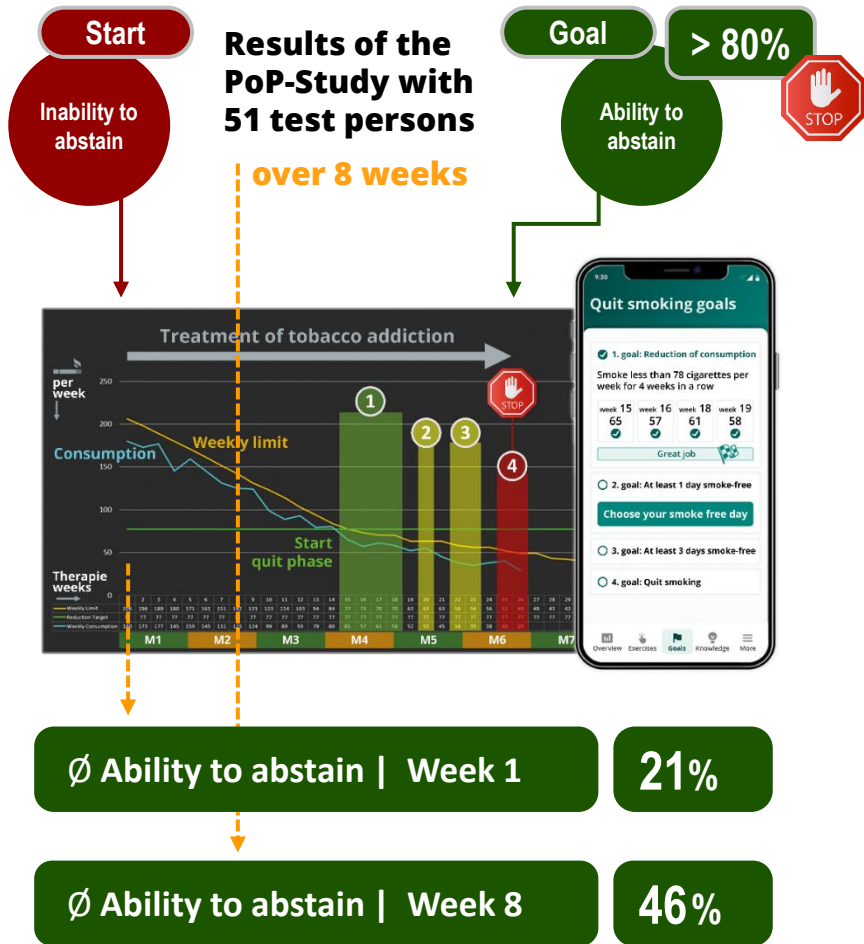


Overload
Quitting phase is extended e.g.: Quitting phase begins after 10 months
Success takes priority over speed!

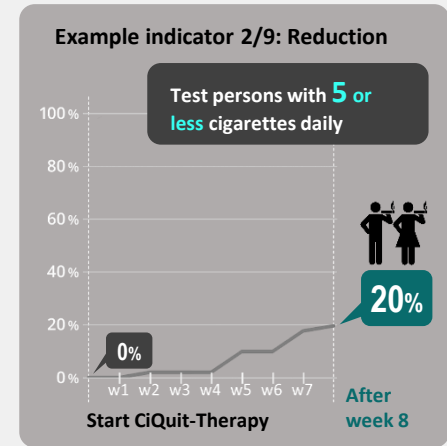
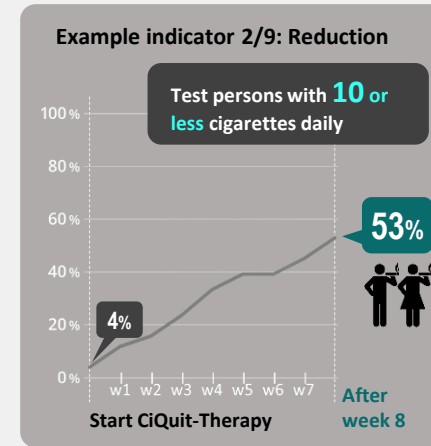
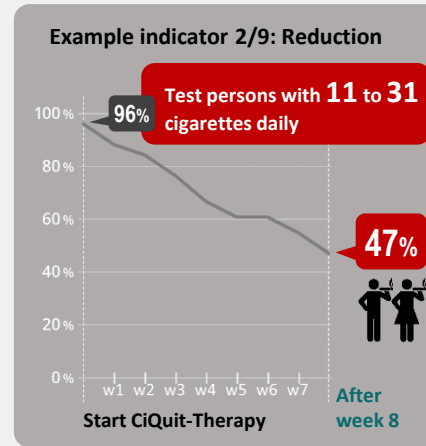


The successful study

Proof-of-Principle Study (PoP-Study)

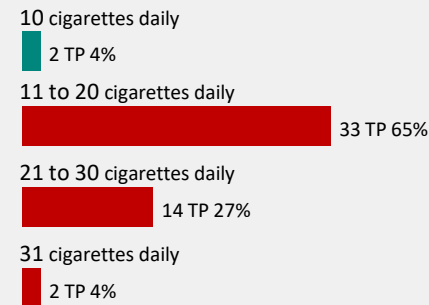


Significant improvements were observed in all 9 indicators of ability to abstain after just 8 weeks!



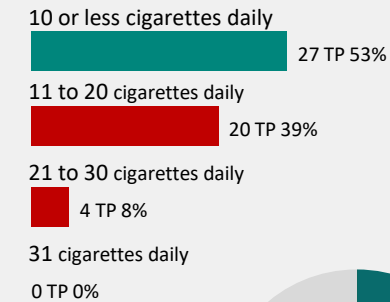
51 test persons (TP)

Start



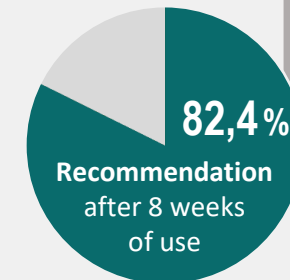
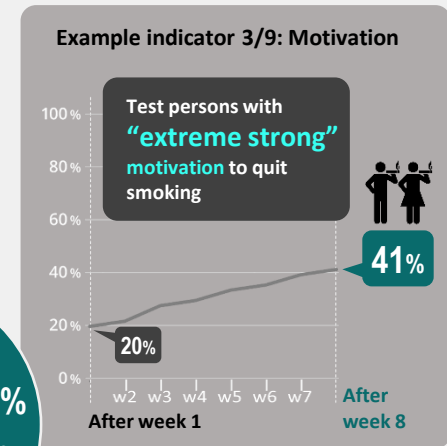
51 test persons (TP)

Week 8



Proof-of-Principle Study

All results at www.luna-medical.com/en/pop-study/



1.3 The summary | Problem/Solution 1/5



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

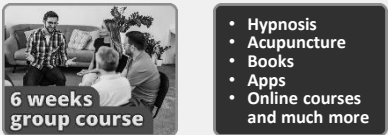
Previous treatment approach

- 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

Solution Quit smoking with ability to abstain

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

Quit smoking "now"! - In the context of the Rubicon model

Rubicon model Part 1

Extrinsic motivation
or intrinsic motivation

Rubicon model Part 2

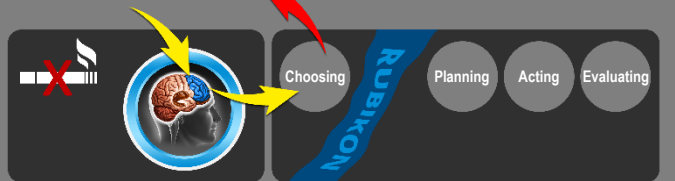
Quit smoking "now"!

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!

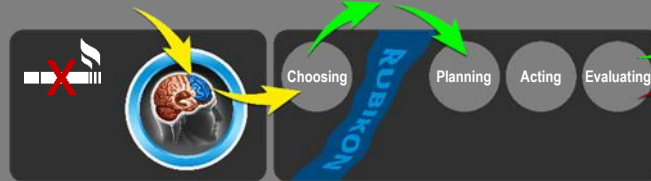
Quit smoking despite inability to abstain

Fear of
"withdrawal symptoms"!

Concern: My suffering will be great and
long-lasting

- Less preparation
- Fear of loss
- Fear of failure

The Rubicon is
nevertheless crossed



Yes, I will!

"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."¹



Prof. Dr. Stephan Mühlig

Stephan Mühlig
Head of the Psychotherapeutic University
Outpatient Clinic TU Chemnitz


**Permanent
abstinence** ✓

**Low
success rates**

Next attempt to quit smoking is usually
postponed for years

Low 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% who used NRT no longer smoked. 11% who used a placebo no longer smoked.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/076-0061_S3_Rauchen-_Tabakabhaengigkeit-Screening-Diagnostik-Behandlung_2021-03.pdf
 5) Source: <https://drks.de/search/de/trial/DRKS00025933> | Basic results | Conclusions
 6) Source: <https://www.cochrane.de/news/ein-neuer-cochrane-review-untersucht-die-wirksamkeit-von-unterschiedlichen>
 7) Source: <https://www.stiftung-gesundheitswissen.de/wissen/rauchentwohnung/koennen-nikotinplaster-und-co-bei-der-rauchentwohnung-helfen>
 8) Source: <https://www.stiftung-gesundheitswissen.de/wissen/rauchentwohnung/kann-vareniclin-bei-der-rauchentwohnung-helfen>

9) Source: <https://www.stiftung-gesundheitswissen.de/wissen/rauchentwohnung/kann-bupropion-bei-der-rauchentwohnung-helfen>
 10) Source: https://register.awmf.org/assets/guidelines/076-0061_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

Smoke "less" first! - In the context of the Rubicon model

Rubicon model Part 1 → **6 month** (Basic setting)
Or adaptation to the weaning progress.

Rubicon model Part 2

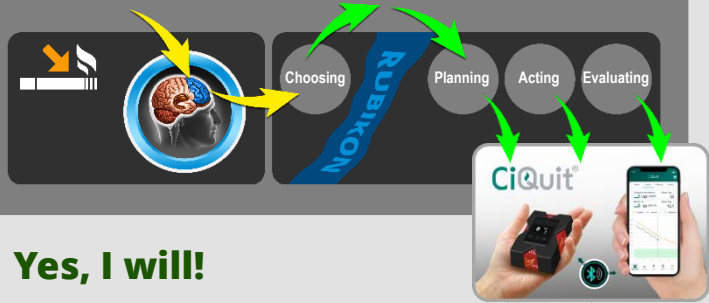
Smoke "less" first!

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**



Quit smoking with ability of abstain

Developing an "anticipation" of a smoke-free life!

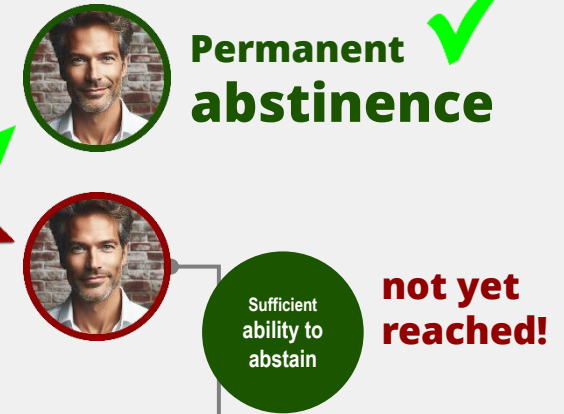
Self-confidence: Smoke-free is a gain in quality of life

• Optimal preparation
• No fear of loss
• No fear of failure

The Rubicon can be crossed **immediately**



- The CiQuit therapy is based on the so-called Rubicon model by Heckhausen and Gollwitzer, a motivation psychology process model that promotes goal-realizing actions through personal resources.
- The therapy guides willing smokers through various stages of maturation— from the conscious desire to quit, through continuous partial successes, to the ultimate goal of lasting abstinence.

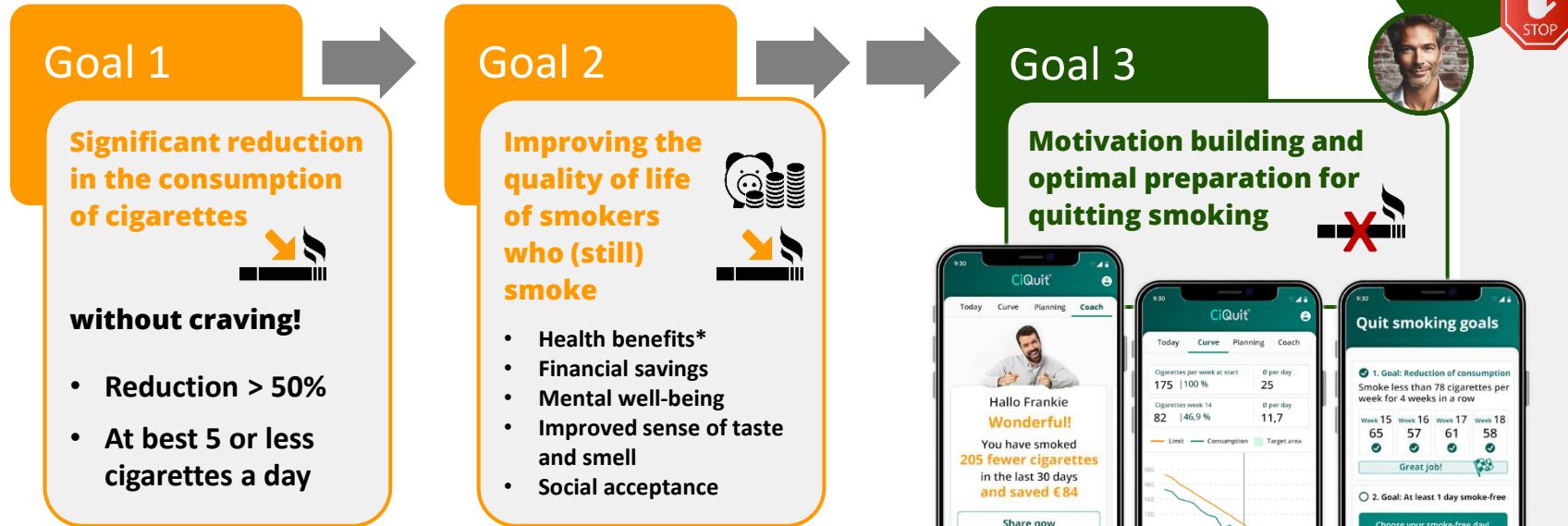


Continuation of the CiQuit Therapy

The solution CiQuit®

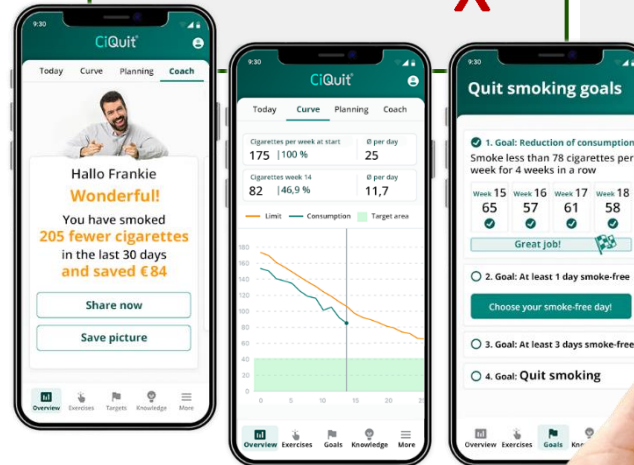
Stepwise **reconditioning** of smoking behavior by unlearning the mental and physical dependency.

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



Reconditioning with CiQuit-Box and CiQuit-App

- CiQuit aims to reduce dependence on cigarettes as a source of "happiness hormones" and instead, as with non-smokers, establish everyday experiences as the new reward.
- Even achieving self-set goals, such as consciously refraining from smoking a cigarette or adhering to smoking limits, generates a sense of pride that triggers the release of "happiness hormones" and positive emotions.
- These positive experiences establish a new **"SMOKE-FREE"** reward system in the **"hot system"**, which perceives the chosen path as promising and motivates the continuation of the CiQuit application.
- As a result, abstinence is not only seen as achievable but also as satisfying, which inevitably increases the likelihood of a successful smoking cessation.



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



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. The effectiveness of CiQuit

Reconditioning



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*

A graphic for CiQuit. At the top left is the CiQuit logo. To its right is the text "Smoking 'delete!'" in large blue font. Below the logo are two circular icons: one with a lit cigarette and another with a brain and the text "hot system". To the right of these icons is a blue silhouette of a firefighter kneeling and using a hose. Below the firefighter are three stacked red rounded rectangles containing the text "Subconscious actions", "Reward centre", and "Addiction centre".

CiQuit®

Smoking "delete!"

hot system

Subconscious actions

Reward centre

Addiction centre

The primary task of CiQuit ...

... reconditioning



The "cool system" must be activated with every reach for a cigarette; only then can the smoking process, which is driven by the "hot system", be reconditioned, meaning unlearned, and non-smoking relearned!



The CiQuit-Box activates the "cool system" with every reach for a cigarette



CiQuit®

Fireman "activate!"



- Planned decisions
- Learning and unlearning
- Reconditioning

The patented technology

CiQuit®



Die CiQuit-Box Activates the "cool system"

1. Behaviour control on the display
3. Hierarchical reduction

Day 1 Limit		25
Day 90 Limit		13
Day 180 Limit		7



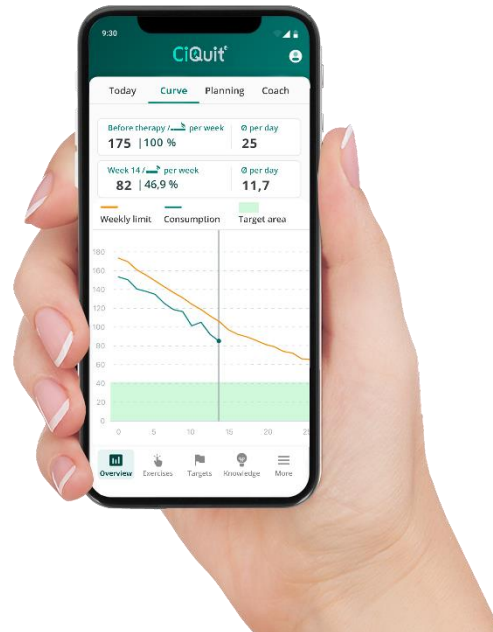
2. Therapy-controlled access delay



Data exchange
All saved data are **automatically** transferred to the app.

Die CiQuit-App

- Visible partial successes
- Motivation
- Roadmap to abstinence
- AI-generated therapy adjustments are transmitted from the app to the box

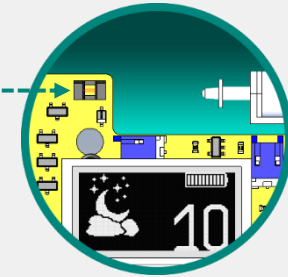


Suitable for everyday use

- No smoker would make an app entry or keep a tally sheet for every cigarette over a longer period of time.
- If the box is ever forgotten, smoked cigarettes can alternatively be entered in the app.

Data exchange

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



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!

The core principle of CiQuit

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

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



The "hot system" is activated through subconscious processes. It generates a craving to satisfy needs that give us a good feeling in the moment. How this behaviour affects us in the long term is not considered by the "hot system".

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



The "cool system" makes planned decisions and can realize learning and unlearning processes. It is able to soberly weigh the pros and cons of alternative courses of action.

The "cold system" must be activated when reaching for a cigarette; only then can the smoking impulse, which originates from the "hot system", be counteracted.



1. Scientific fact



A planned change in behaviour is not possible without observing the problematic behaviour and recording the results.

"Simply observing your own smoking behaviour leads to a significant reduction in smoking."

Rainer Tölle, Gerhard Buchkremer - Cigarette smoking: Epidemiology, psychology, pharmacology and therapy

The display directly on the cigarette pack

provides smokers with information about their daily smoking behaviour.

- This means that smoking does not happen unconsciously and automatically, as the smoker has the opportunity to check their smoking intention before lighting up.
- **Suitable for everyday use:** Automatic consumption recording - no smoker would permanently record every cigarette in an app or keep tally sheets.

Behavioural control when reaching for a cigarette



Today smoked

The previous consumption is displayed before each cigarette.

Just available

The box can be opened after the access delay as long as this value is greater than 0.

Later available

This value shows how many additional cigarettes are available until the evening.

"Later available" cigarettes are transferred throughout the day after **"Just available"**.

2. Scientific fact



"The positive aspect is that smoking as a learned behaviour can also be unlearned.

New behavioural patterns and coping strategies can be practiced.

Interrupting automated behaviour is one of the decisive factors."

*Ilse Müller,
Psychotherapist (behavioural therapy), focus on nicotine addiction, among other things*

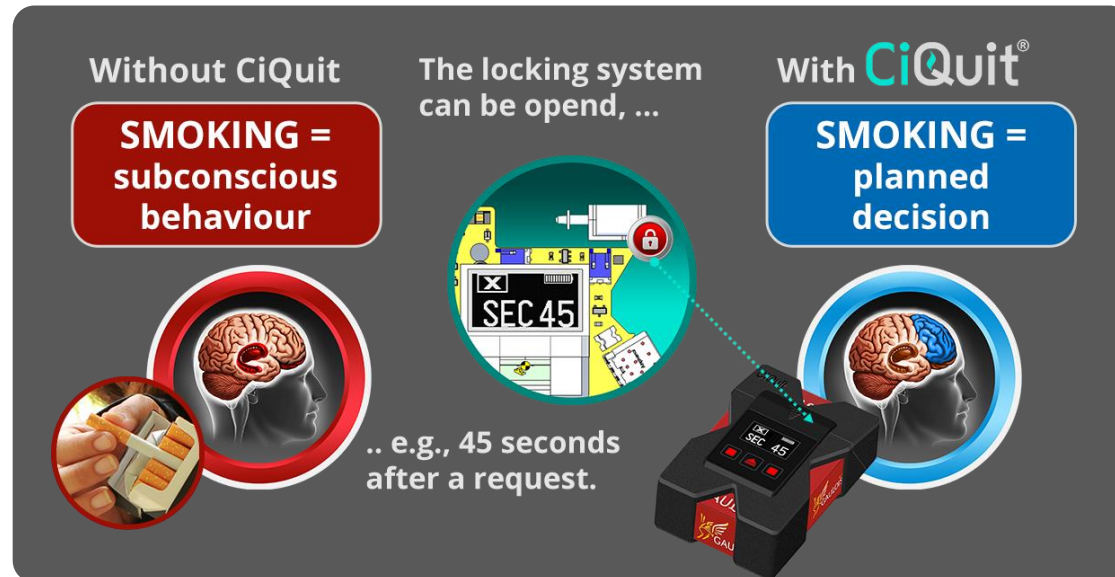


Planned decisions

Learning and unlearning

Reconditioning

Access delay when reaching for a cigarette



Access delays slowly increasing daily!

Examples:

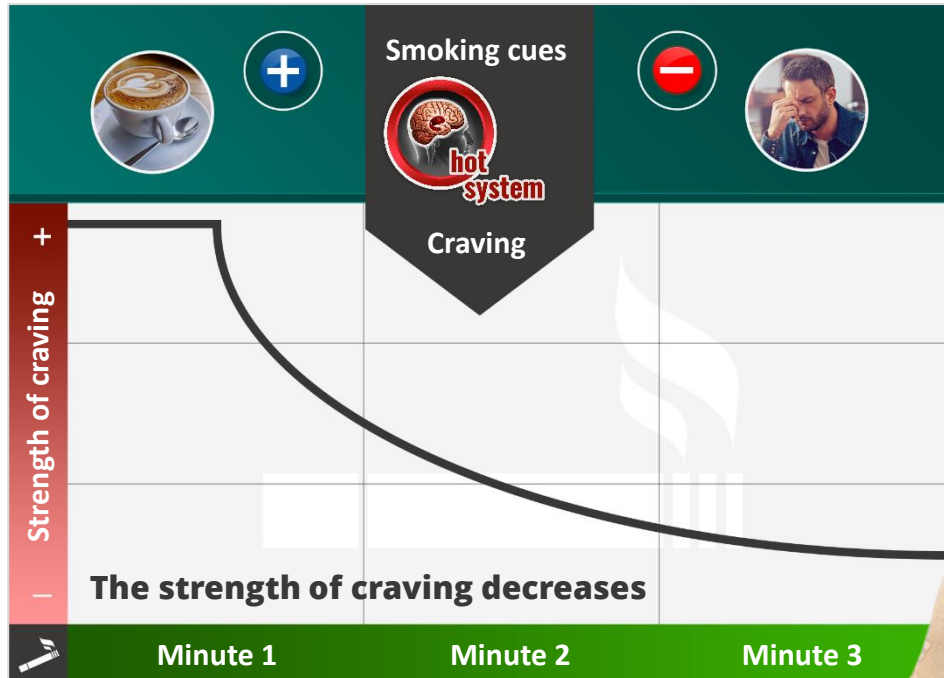
Day 1
20 seconds

Day 39
1:17 minutes

Day 83
2:46 minutes

The access delay

- The brain learns that craving and nicotine satisfaction are becoming more and more separate!
- After about 30 seconds, the craving usually becomes weaker, and it becomes easier to abstain from smoking this cigarette!



During the **access delay**, smokers do not feel any craving pressure. The body and mind adapt to the slowly increasing access delays.

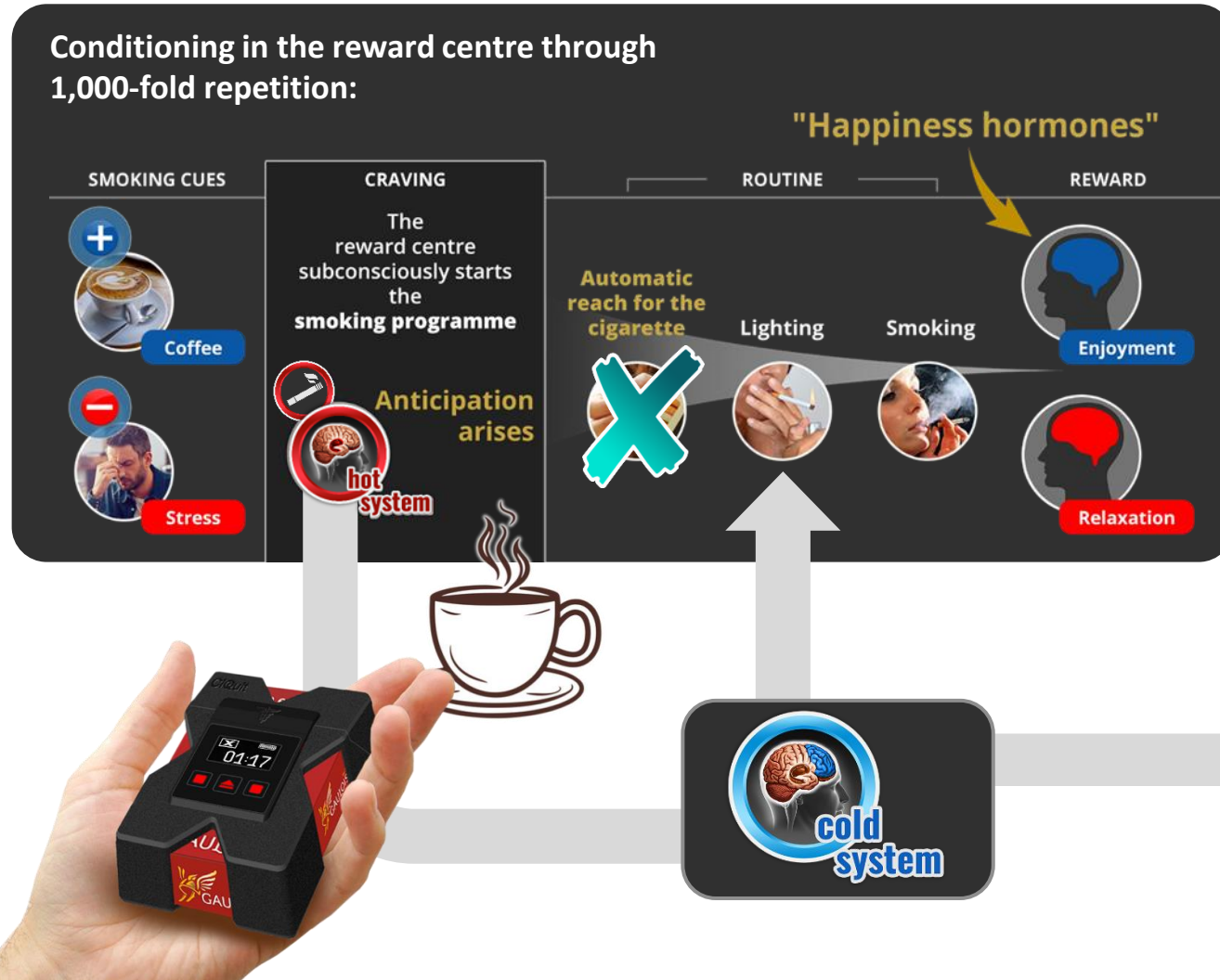
No addiction pressure



What addiction experts say!

- Such cravings usually only last a short time compared to the periods when you no longer feel like having a cigarette. After 30 seconds to three minutes, the craving almost always subsides.¹
- The craving usually only lasts one to three minutes.²
- Realize that it's only a few minutes that you have to get through.³
- **With every craving attack that you resist, your brain and body learn that you can do without it.**⁴

The access delay - summary



Primary Goal

Timeframe for a planned and conscious decision:

1. Smoking? **No**
2. Alternative action from the app? **Yes/No**
3. Smoking? **Yes**

With each craving attack and every trigger where a cigarette is avoided, both body and mind learn that daily life can function without smoking.

Reconditioning



3. Scientific fact



"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*

- Planned decisions
- Learning and unlearning
- Reconditioning

„Reduction treatments ...

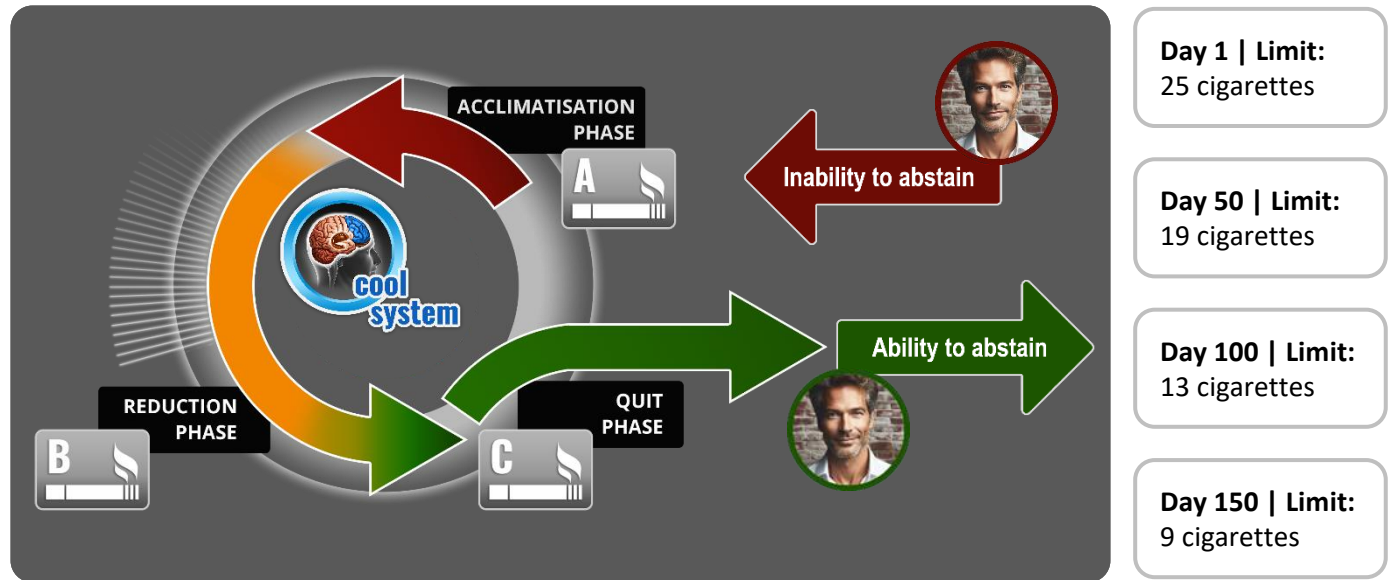
... are aimed at people who are willing to change but are unable or unwilling to lead an abstinent lifestyle. Various field studies, randomised control group studies and meta-analyses have shown **that significantly more people are willing to reduce than to abstain ...**

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

Hierarchical reduction when reaching for a cigarette



Slowly decreasing daily limits every week!
Example - Start with 25 cigarettes a day:



A = **Weak**

- Conditioning
- Craving

B = **Medium**

- Conditioning
- Craving

C = **Strong**

- Conditioning
- Craving

As a result, CiQuit ensures that reconditioning during the gradual reduction is carried out according to a target-oriented system.

Rapid reduction successes and building up the motivation to reduce by simply giving up A-cigarettes and more easily giving up B-cigarettes.

Step by step, the application teaches the brain to cope with "critical smoking situations" without a C-cigarette.

"In situations where a smoker's conditioned brain expects nicotine, a craving to smoke automatically occurs. Developing skills to cope with smoking cravings is a central element of cognitive-behavioral therapy approaches.

In the **traffic light model**, three phases of smoking craving are distinguished:



= Weak

- Conditioning
- Craving



In the green phase, the addiction pressure is mild and only weakly perceived. In this phase, most smokers manage to cope with the craving by ignoring it without the need for additional help.

A-cigarettes, for example, are the second or third cigarettes smoked in succession. The second or third cigarette is only weakly associated with a triggering stimulus. Giving them up does not pose a significant challenge. The body has already received nicotine from the first cigarette, and the smoking reward system has already been engaged by the first cigarette as well.



= Medium

- Conditioning
- Craving



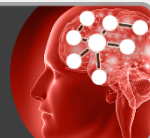
In the yellow phase, the craving becomes more noticeable as addiction pressure, and the smoker experiences restlessness and lack of concentration. In this phase, the prefrontal cortex still retains control over the emotion center, which continues to increase the addiction pressure. Many smokers find it helpful to use specific techniques such as distracting activities, alternative behaviors, or breathing exercises to deliberately change their thoughts and/or physical state.

B-cigarettes relate to smoking situations that occur infrequently and therefore are only minimally to moderately ingrained as a habit. For example, people might enjoy smoking to pass short waiting times. Giving up this cigarette is not too difficult because the brain typically only has a weak to moderate association between waiting and smoking. A contrasting example would be a taxi driver who smokes, where the situation of waiting for the next customer and smoking is very strongly linked.



= Strong

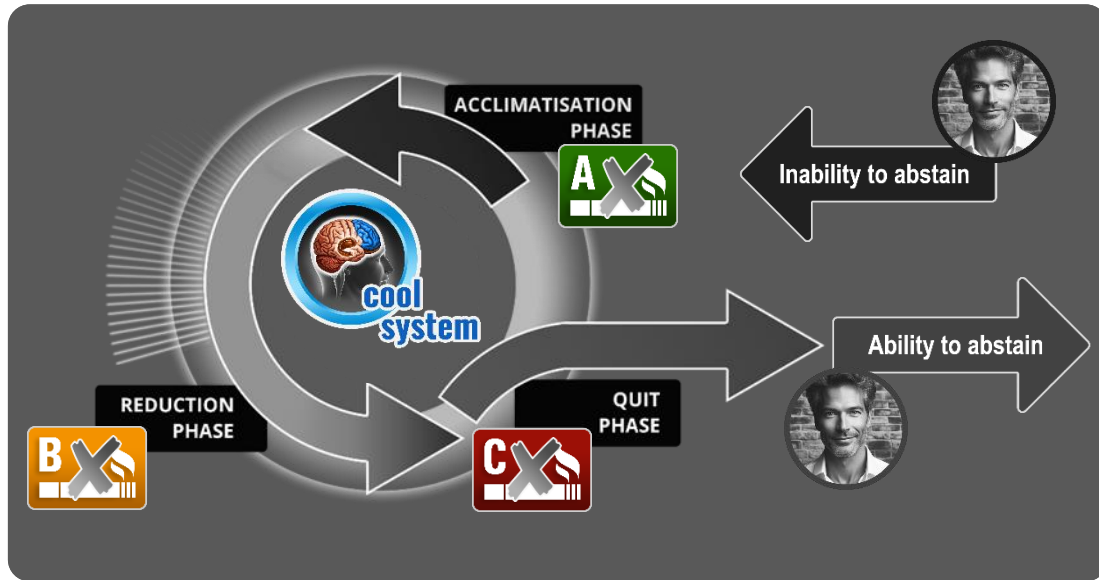
- Conditioning
- Craving



In the red phase, the addiction pressure becomes increasingly intense until the smoker can no longer clearly control their thoughts. In this phase, active engagement, stimulating the senses, as well as actively addressing and questioning the feelings experienced during the addiction pressure can help manage the temptation situations (Szasz et al. 2012)."

C-cigarettes are deeply ingrained as a habit because they are repeated thousands of times. Examples include the morning cigarette with coffee, smoking during stressful situations, when others are smoking, after meals, or in conjunction with alcohol. It is precisely these cigarettes that make quitting smoking so difficult and contribute to high relapse rates.

Treatment strategy



The patented behaviour control enables the smoker, who is willing to quit, to use the remaining and permitted cigarettes for their "critical smoking situations." It is precisely in these smoking situations (C-cigarettes) that the unlearning process (including the disassociation of the triggering stimulus and the cigarette) is most effective in the relevant brain areas.

Behaviour control via the display directly on the cigarette pack.

Smoked today			2
Just available			3
Later available			8

The hierarchical reduction offers crucial advantages for a permanent cessation of smoking:

1. Rapid development of the "SMOKE-FREE" reward system
2. The smoker willing to quit gradually loses the fear of having to cope with negative emotions without a cigarette and learns to enjoy positive situations again without a cigarette.
3. Step by step, the smoker willing to quit comes to the realization that they do not have to give up something "valuable" for the rest of their life.

Three crucial mental factors that motivate smoking cessation and promote successful abstinence!

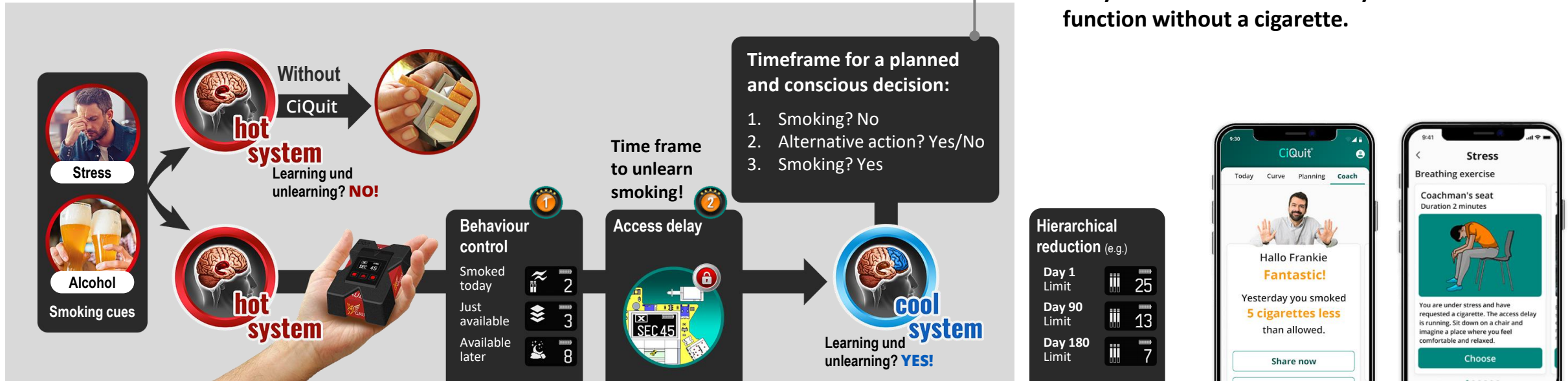


3. The summary of the CiQuit-System

- **The primary task of the CiQuit-Box**
- **The primary task of the CiQuit-App**
- **The primary task of the CiQuit-System**



The primary task of the CiQuit-Box



With every craving and every smoking cue where a cigarette is foregone, both body and mind learn that daily life can function without a cigarette.

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	Day 39	Day 83
20 seconds	1:17 minutes	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.

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."

The primary task of the CiQuit-System

Psychological dependence

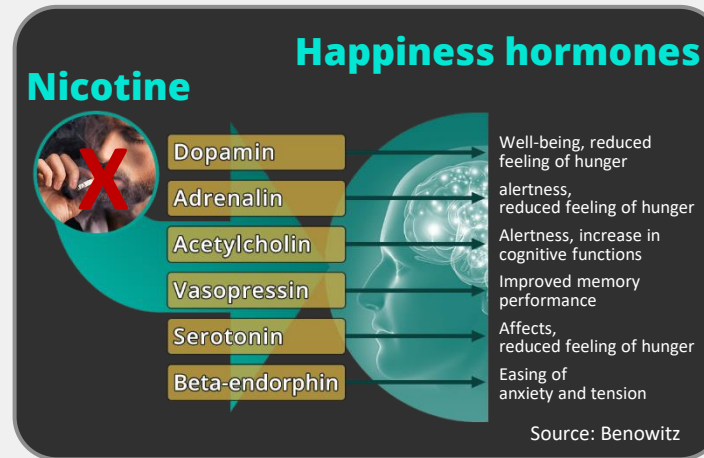
Reconditioning without pressure of addiction



- The functions of the CiQuit Box directly on the cigarette pack, particularly behavior control and access delay, effectively separate the smoking cues from the cigarette.
- With each craving attack and each smoking cue, when a conscious decision is made to refrain exact this cigarette, the body and mind learn that daily life can function without a cigarette.
- The patented transformation of the smoking process from a subconscious action "hot system" to a planned decision "cool system" is crucial in this regard.

Psychological dependence

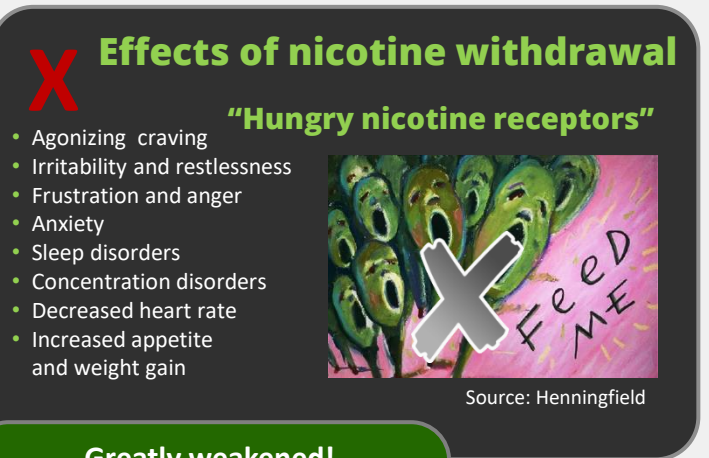
Reconditioning without pressure of addiction



- Step by step, CiQuit effectively helps overcome mental dependence and lead a more content life without cigarettes.
- The goal is to recondition the reward system so that the pleasure derived from healthy and constructive activities replaces the perceived nicotine reward (pleasure, relaxation).
- Additionally, CiQuit motivates engagement in sports, social interactions and hobbies, which in turn release natural "happiness hormones".

Physical dependence

Minimise Fagerström score (FTND)



Greatly weakened!
At best, no longer available.

- The FTND primarily measures physical tobacco dependence, where a low score correlates with high chances of success.
- CiQuit aims, among other things, to reduce early morning smoking and daily cigarette consumption, as these two indicators significantly influence the FTND score.
- Physical dependence can usually be overcome in a few weeks. However, psychological dependence, often deeply rooted in habits and social rituals, requires comprehensive reconditioning.

4. Visibility of the CiQuit-System in the target group



Visibility of the CiQuit-System in the target group 1/1

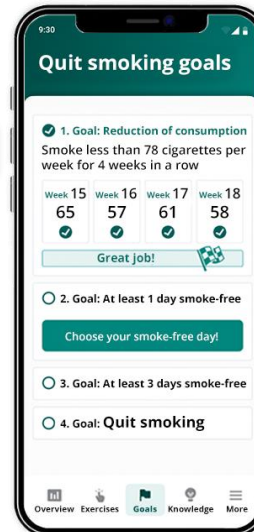
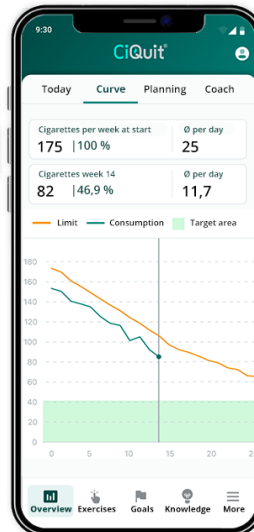
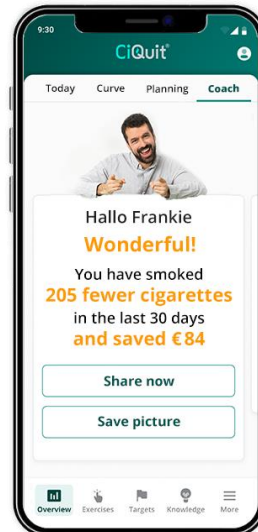
Experience shows that every CiQuit user is immediately approached by other smokers about the **CiQuit-Box**.

Other smokers are asking:

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



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

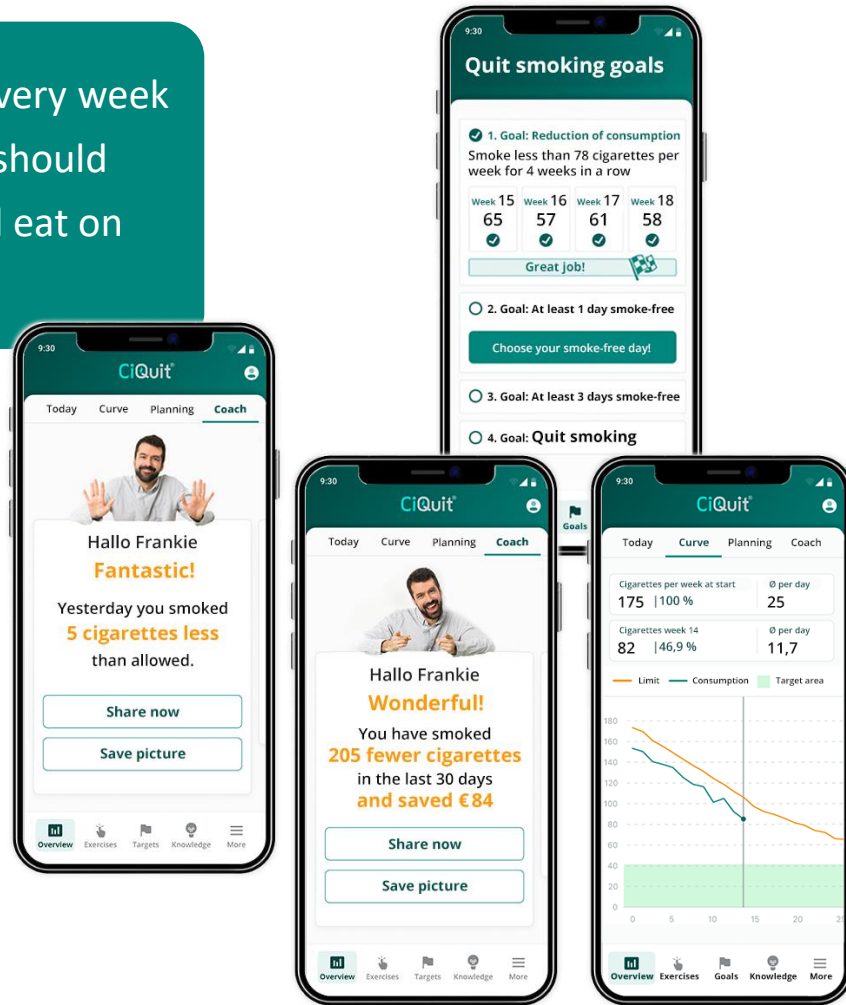


5. The adherence to the CiQuit-System



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.

Worth knowing

Appendix 1: Barriers to utilizing offers of help	52
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Tobacco consumption

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



Further PDF documents



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

Appendix 1

Barriers to utilizing offers of help

- Effort
- Side effects
- Costs





CiQuit has no or only low usage barriers

 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.

 **Germany**
 Cost coverage **NO**
8%

Using NRT during an attempt to quit smoking

 **England**
 Cost coverage **YES**
48%

Using NRT during an attempt to quit smoking

¹ Subscription model for self-payers

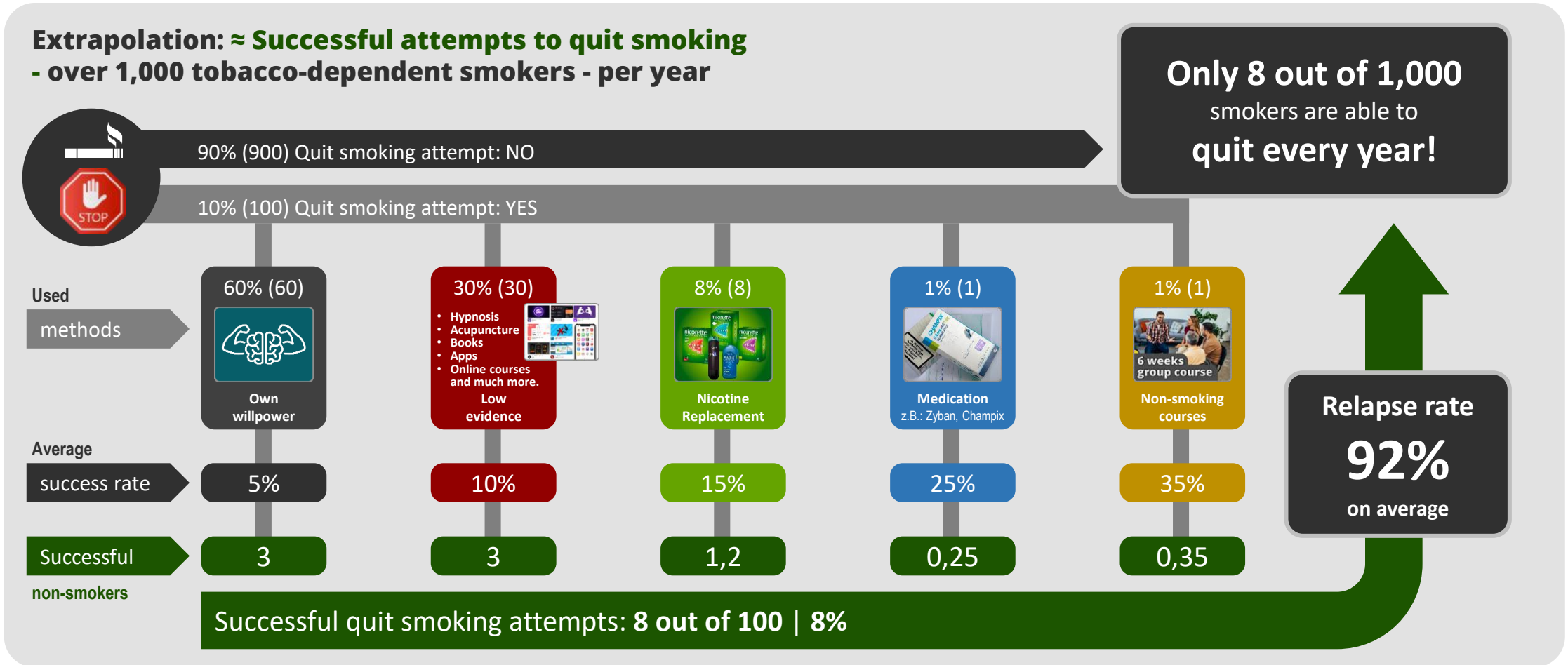
² as DiGA = Digital Health Application according to MDR I

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>

Appendix 2

High relapse rates despite many offers of help

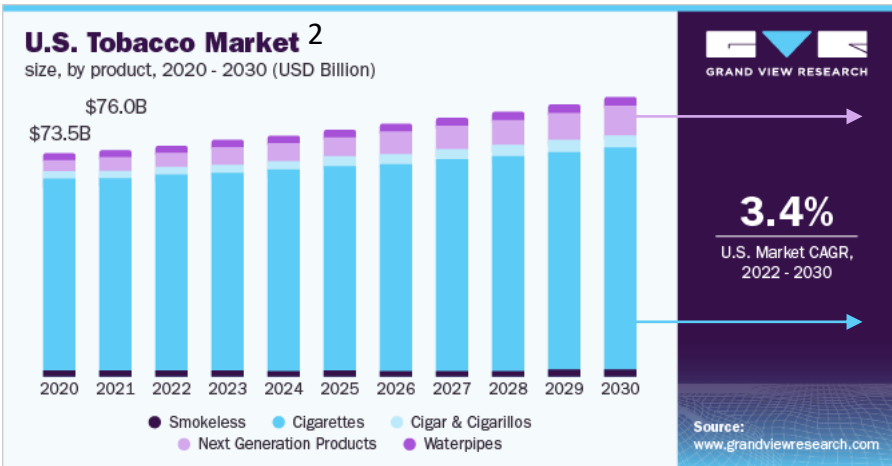
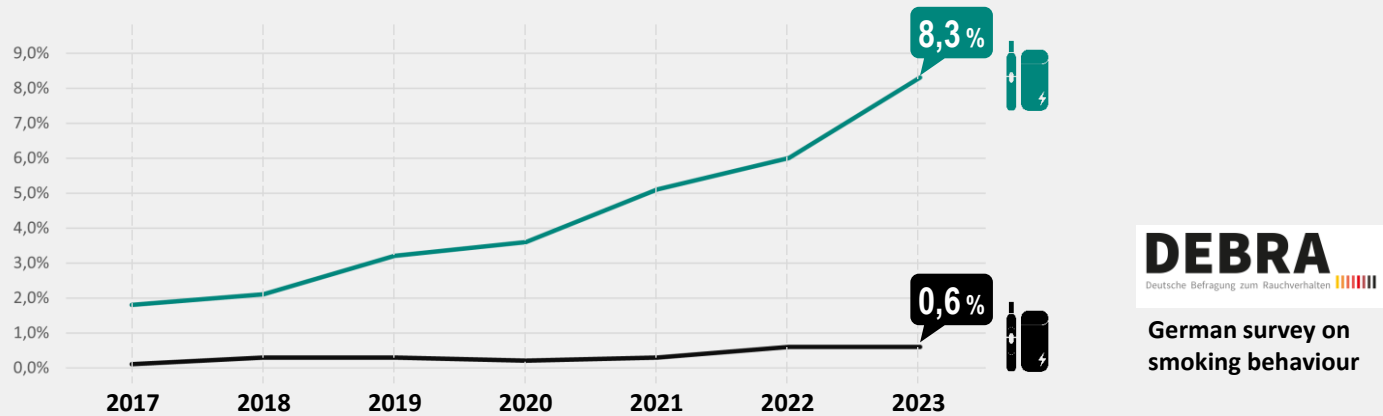
Far too few smokers achieve the leap into permanent abstinence each year.



Appendix 3

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



Tobacco heaters and E-cigarettes*



Traditional cigarettes



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

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

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

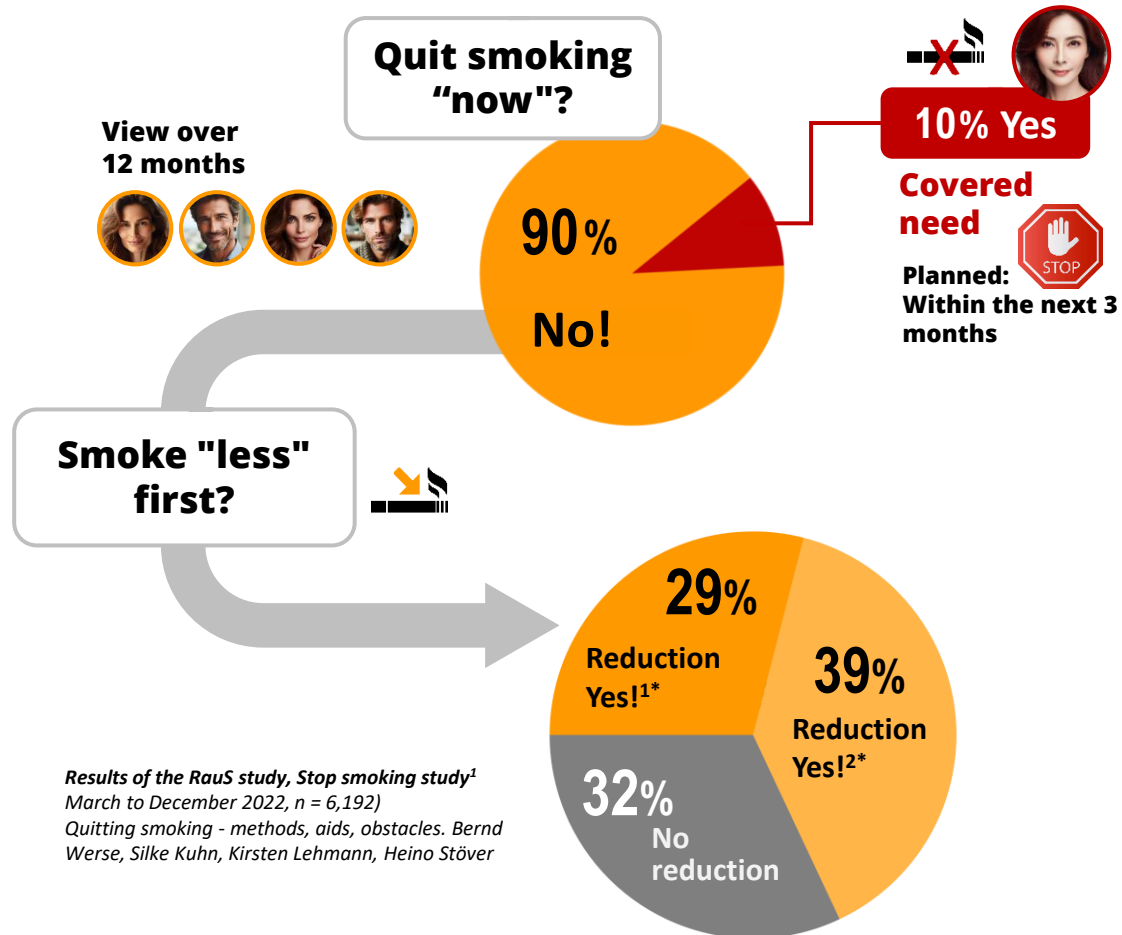
1) Source: <https://www.debra-study.info/>

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

Appendix 4

CiQuit - The enormous healthcare gap

Uncovered need



1* 29% = Only smoke on certain occasions

2* 39% = Smoke less cigarettes per day

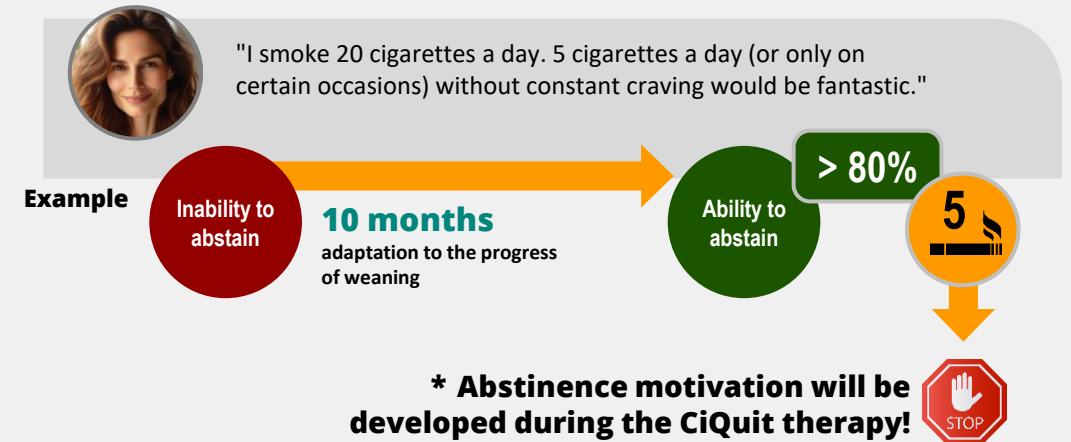
CiQuit[®]

... for the unfulfilled desire

1. The gentle introduction to smoking cessation



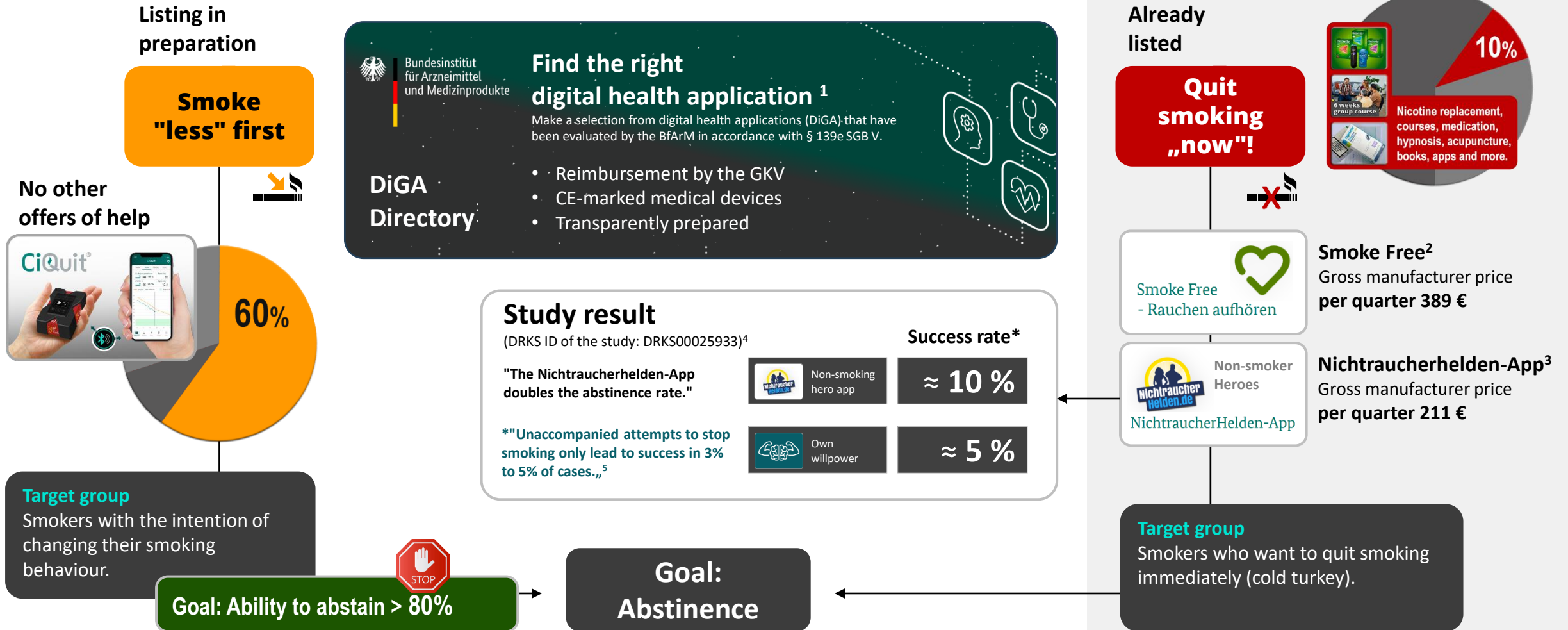
2. The permanent reduction of consumption*



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

CiQuit - And the DiGA directory

Tobacco cessation in the DiGA directory Germany



Explanations on physical (bodily) tobacco dependence

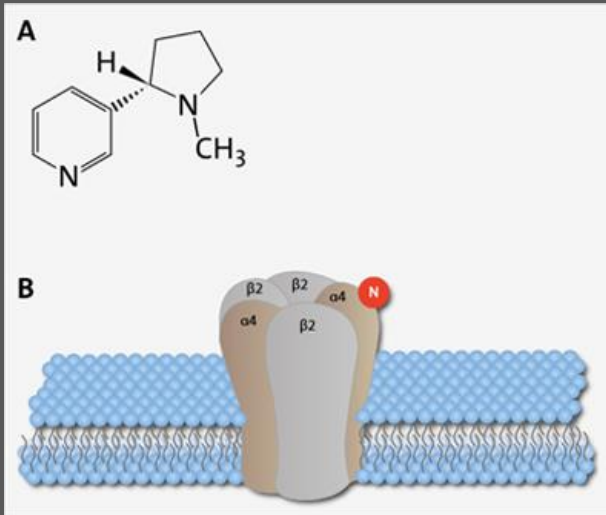


Illustration:
German
Cancer Research
Center,
Cancer Prevention
Unit

A Structural formula of nicotine

B Schematic representation of the structure of a nicotinic acetylcholine receptor (nACh-R)

Current S3 guideline¹

On the other hand, neuroadaptive processes based on an increased density of central nicotinic ACh receptors ... a physical dependence that explains classificatory categories such as "compulsive smoking", "withdrawal symptoms" and "tolerance development".

S3 guideline: p. 31, para. 2, sentence 2

Nicotine withdrawal symptoms²

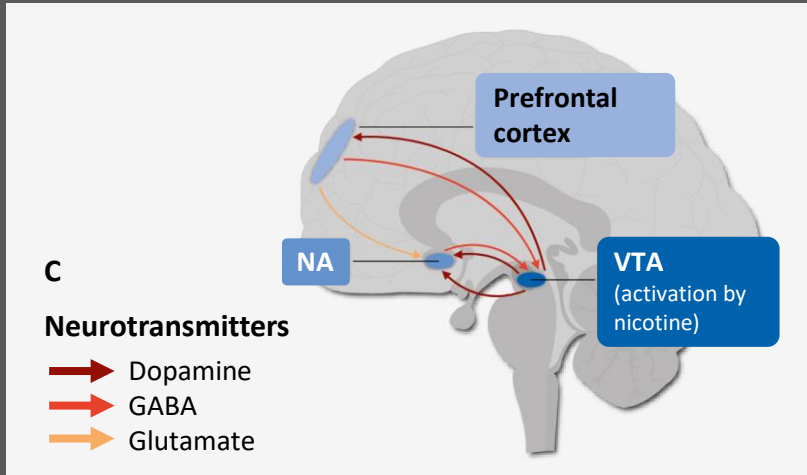
- "Crucial for physical dependence is the effect of nicotine in the brain: It binds to nicotinic ACh receptors, among others on dopaminergic neurons in the ventral tegmental area (VTA), thereby stimulating the release of dopamine in the nucleus accumbens (NA), the brain's reward center.
- Dopamine is a neurotransmitter and facilitates communication between nerve cells. The release of dopamine is supported by the nicotine-induced release of other neurotransmitters in these brain regions, particularly GABA (gamma-aminobutyric acid) and glutamate.
- The increased level of dopamine in the reward center induces a feeling of pleasure. This is the first step into dependence, as the feeling of pleasure promotes further nicotine consumption. With repeated consumption, the brain becomes accustomed to nicotine and develops a tolerance, leading to physical dependence and withdrawal symptoms.
- As a result of chronic nicotine intake, existing nicotinic ACh receptors become less sensitive (desensitization/inactivation), making it increasingly difficult to stimulate the reward center, as only high amounts activate a desensitized or inactive receptor.
- Counteracting the tolerance is the increased formation of new nicotinic ACh receptors. This surplus of nicotinic ACh receptors is dose-dependent and causes withdrawal symptoms: As soon as a critical number of ACh receptors is no longer occupied by nicotine (about four to six hours after nicotine consumption), a stress hormone (corticotropin-releasing factor, CRF) is released.
- **This activates the extended amygdala, a brain area that mediates withdrawal-typical moods such as irritability, lack of drive, depression, inner restlessness, and anxiety.**
- Thus, the dependence initially feeds on the desire for the quick, dopamine-mediated feeling of pleasure. Later, the desire to restore the normal state and avoid physical withdrawal symptoms prevails."

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

2) Source: https://www.dkfz.de/de/tabakkontrolle/download/Publikationen/FzR/FzR_Gesundheitsrisiko_Nikotin_web.pdf | p. 3

Explanations on psychological (mental) dependence

Illustration:
German
Cancer Research
Center,
Cancer Prevention
Unit



C In the brain, nicotine binds to nACh receptors in the ventral tegmental area (VTA), which causes the release of dopamine. This dopamine acts on the nucleus accumbens (NA) and the prefrontal cortex, leading to the release of other neurotransmitters such as GABA and glutamate. The activation of the prefrontal cortex and other brain areas associated with learning and memory leads to the development of psychological dependence.

Current S3 guideline¹

As a chronic disease, tobacco addiction has a high risk of relapse. A strong desire to smoke (craving) is a major factor in relapses.

S3 guideline: p. 49, para. 3, sentence 2

Conditioning with Smoking cues



Craving²

- At the same time as the nicotine-induced dopamine release in the reward center, dopaminergic pathways stimulate an area in the prefrontal cortex involved in learning processes.
- The peril of this is that smoking, and its perceived positive effects become associated with certain situations (the morning cup of coffee, a good meal, or a conversation with friends, a visit to a bar) as well as actions related to smoking (taking out a cigarette), sensory perceptions while smoking (smell, taste, feeling of the smoke in the throat), and affective states (stress, sadness).
- The repeated association alters neuronal connections in the brain, resulting in a long-lasting conditioning to these stimuli.
- **This leads to psychological dependence and makes quitting so difficult because certain stimuli and situations alone can trigger the craving for a cigarette.**

1) Source: https://register.awmf.org/assets/guidelines/076-006L_S3_Rauchen-Tabakabhaengigkeit-Screening-Diagnostik-Behandlung_2021-03.pdf
2) Source: https://www.dkfz.de/de/tabakkontrolle/download/Publikationen/FzR/FzR_Gesundheitsrisiko_Nikotin_web.pdf | p. 3

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.