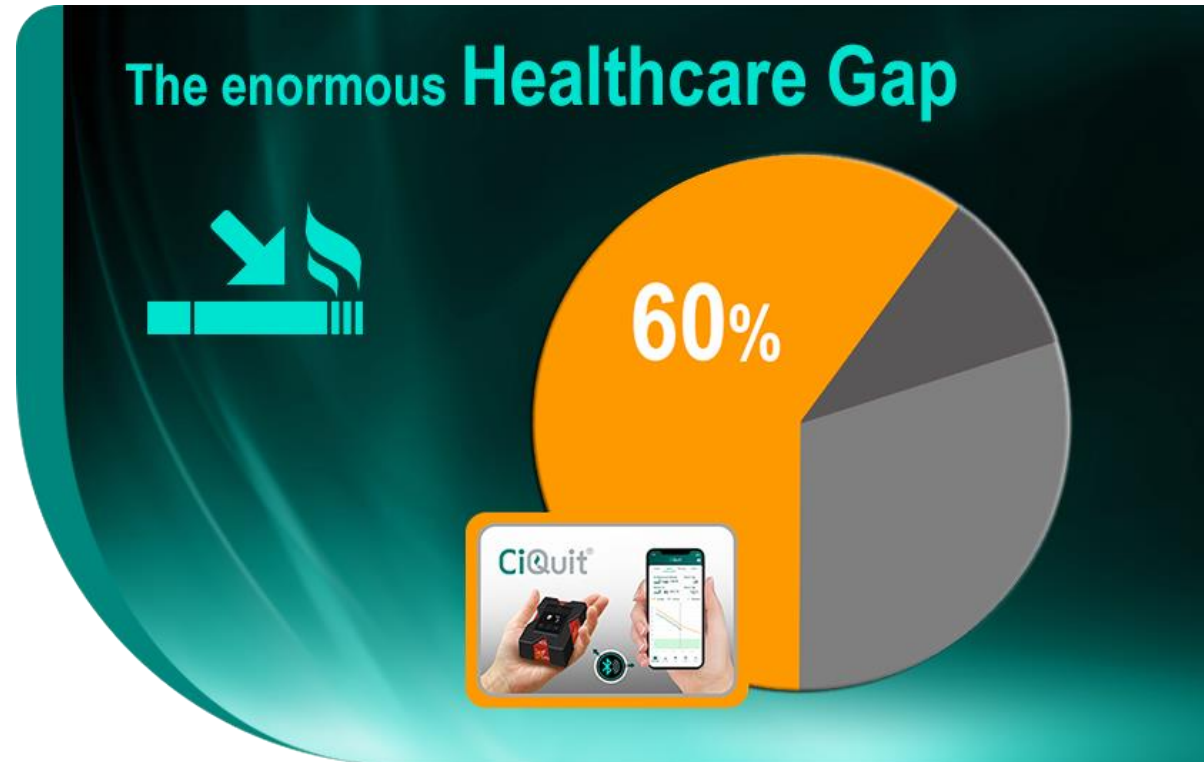




The Healthcare Gap - Smoke “Less” First!

Taking Germany as an example.



Contents

1. Differentiation: “Covered need” vs. “CiQuit”.....	3
2. Our offer for the majority of smokers!	4
3. The healthcare gap = Smoke "less" first!.....	5
4. Large uncovered need	6
5. Rubicon model: CiQuit - The quick decision to use	7
6. CiQuit: No or only low barriers to utilisation	8
7. Visibility of the CiQuit-System in the target group	9
8. Why is the CiQuit box not bypassed?	10
9. Quit smoking “now”! - In the context of the Rubicon model.....	11
10. Quit smoking “now”! - Low success rates	12
11. Smoke “less” first! with CiQuit - In the context of the Rubicon model.....	13
12. Smoke “less” first! with CiQuit - High success rates.....	14

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/>

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

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!



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

"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 ...**²

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

1) Source: https://ensp.network/wp-content/uploads/2020/10/guidelines_2020_english_forprint.pdf | p. 91 ff
2) Source: <https://docplayer.org/45668034-4-1-das-paradigma-zieloffener-suchtarbeit.html> | p. 198

2. 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**.

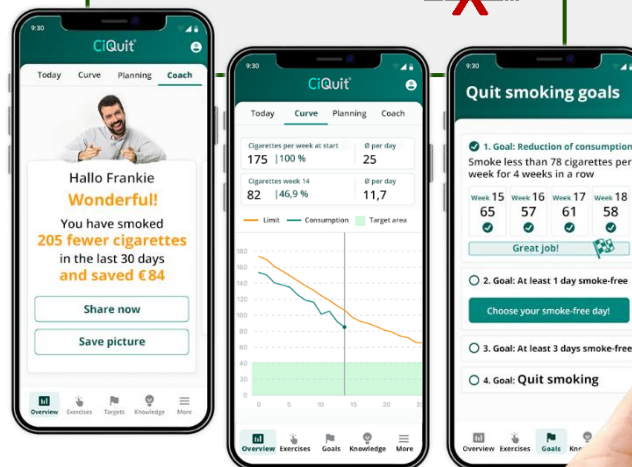


What addiction experts say!

"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*



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

Reconditioning with CiQuit-Box and CiQuit-App



CiQuit®
Reconditioning



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



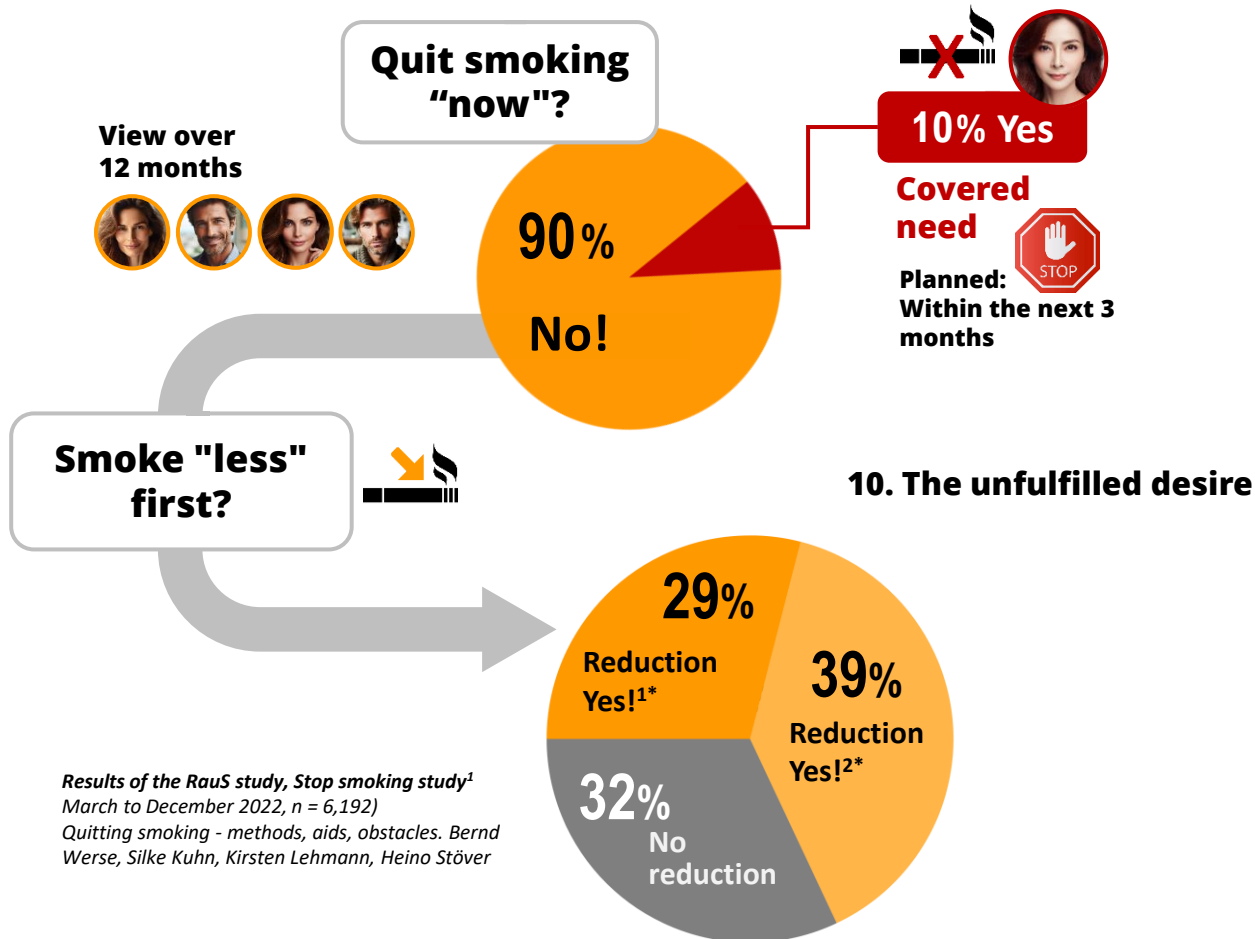
The reduction of smoking ...

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

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

3. The healthcare gap = Smoke "less" first!

The unfulfilled desire



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

1* 29% = Only smoke on certain occasions

2* 39% = Smoke less cigarettes per day



... for the unfulfilled desire

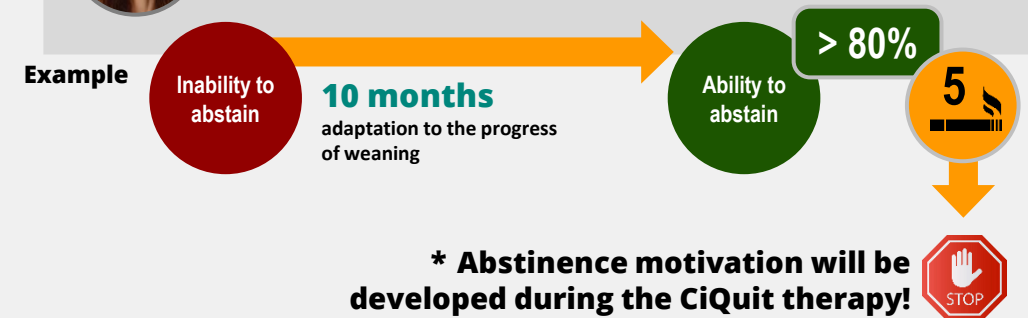
1. The gentle introduction to smoking cessation

Example "I would prefer to gradually smoke less before quitting altogether, making the process as stress-free as possible."



2. The permanent reduction of consumption*

Example "I smoke 20 cigarettes a day. 5 cigarettes a day (or only on certain occasions) without constant craving would be fantastic."



* Abstinence motivation will be developed during the CiQuit therapy!

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

4. Large uncovered need

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

That's what science says!

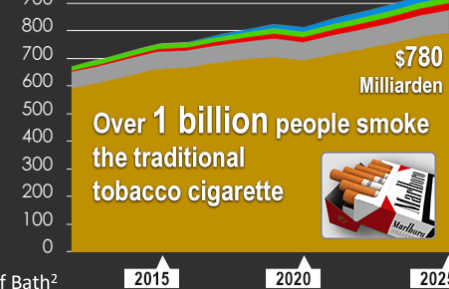
"Glasgow et al. estimate that an additional 22% - 39% of smokers could be reached by a reduction offer.

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

Competitors focus on switching to substitute products or quitting smoking immediately

World Health Organization
Around 1.3 billion tobacco consumers

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



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



Enormous healthcare gap

- Uncovered need
- No need
- Covered need

→ **Covered need** = + +

Offers designed to help replace tobacco cigarettes

Tobacco heater

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

Global sales | Forecast 2030
US\$ 98,7 billion³

E-cigarettes

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

Global sales | Forecast 2030
US\$ 63,4 billion⁴

Offers designed to support the desirable complete smoking cessation.

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

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

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

1) Source: Quelle: https://edoc.uni-muenchen.de/22126/1/Kiss_Alexa.pdf
2) Source: <https://www.van-grunsteyn.com/sektoranalyse-tabak-resilienz-durch-anpassung>

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

5. Rubicon model: CiQuit - 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.

6. CiQuit: No or only low barriers to utilisation

Barriers to utilizing offers of help

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





 High willingness to use

 Low willingness to use

Example Germany 

Target group	Method of implementation	Effort during use	Side effects	Costs	Use of the method in %	Quit smoking attempts per year	Success rate
--------------	--------------------------	-------------------	--------------	-------	------------------------	--------------------------------	--------------

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

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

Uncovered need - Smoke „less“ first!

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

Several goals:

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

Goal: Inability to abstain > 80% 

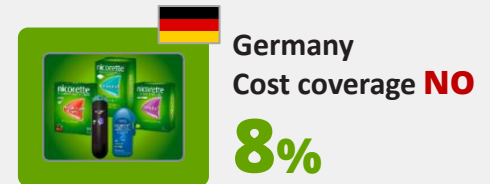
Current S3 guideline¹

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

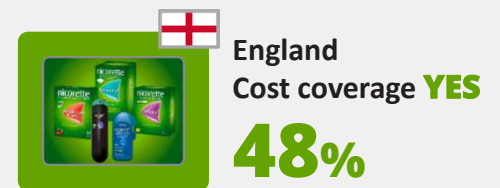
(S3 guideline: p. 97, para. 3, sentence 1)

Comparison of countries²

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



Using NRT during an attempt to quit smoking



Using NRT during an attempt to quit smoking

- 1) Attractive subscription model, costs may be subsidised by health insurance companies and/or employers
- 2) Cost coverage by health insurance companies as DiGA = digital health application according to MDR I

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

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

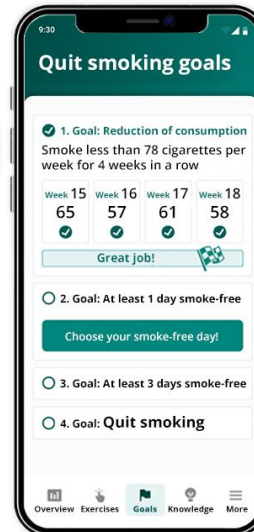
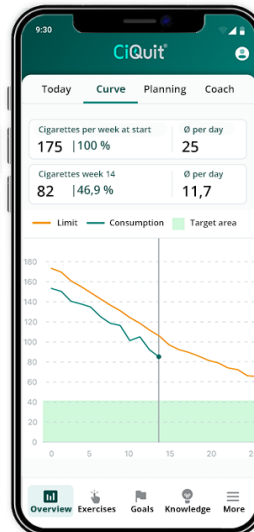
Experience shows that every CiQuit user is immediately approached by other smokers about the **CiQuit-Box**.

Other smokers are asking:

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

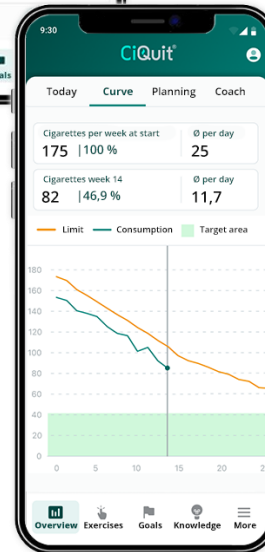
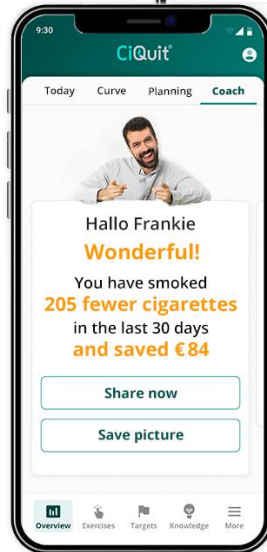
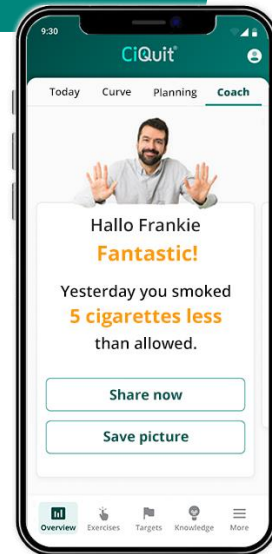


The CiQuit benefit can be communicated very easily via the **CiQuit-App**!



8. 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.

9. 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!

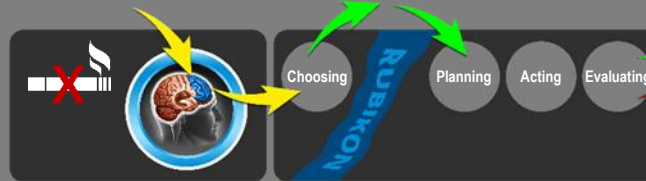
Quit smoking despite inability to abstain

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** ✓

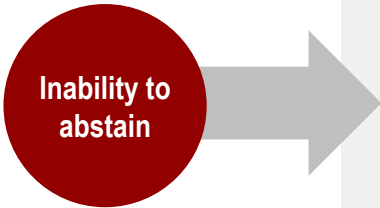
**Low
success rates**

Next attempt to quit smoking is usually
postponed for years

10. Quit smoking "now"! - Low success rates

Problem

The inability to abstain prevents successful smoking cessation!



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



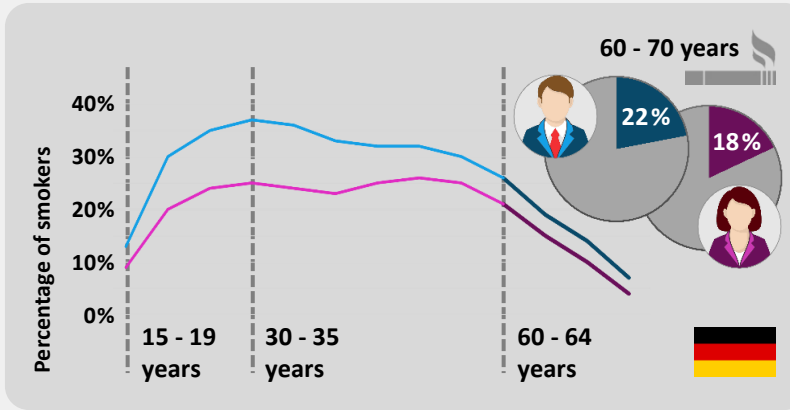
Quelle: J. Henningfield

High level of suffering

High relapse rates (despite help)

Next attempt to quit smoking is usually postponed for years

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



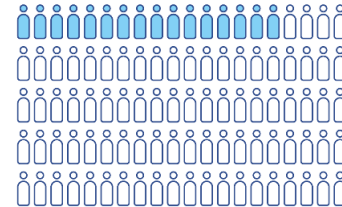
≈ 15 %

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

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>

11. Smoke "less" first! with CiQuit - 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

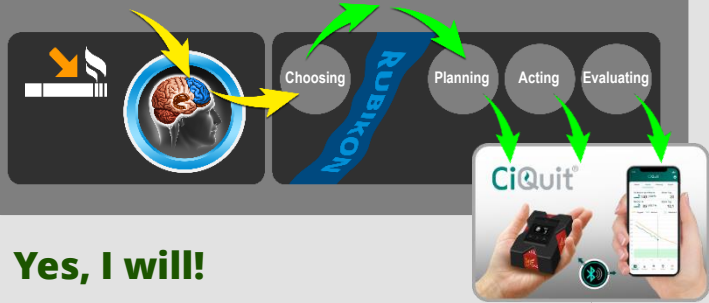
Smoke "less" first!

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**



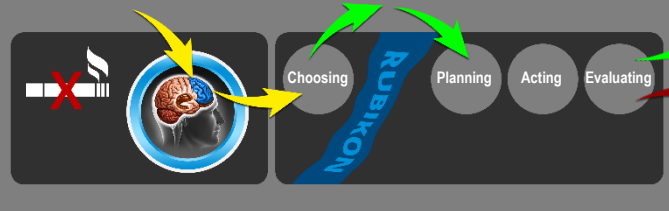
Quit smoking with ability of abstain

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

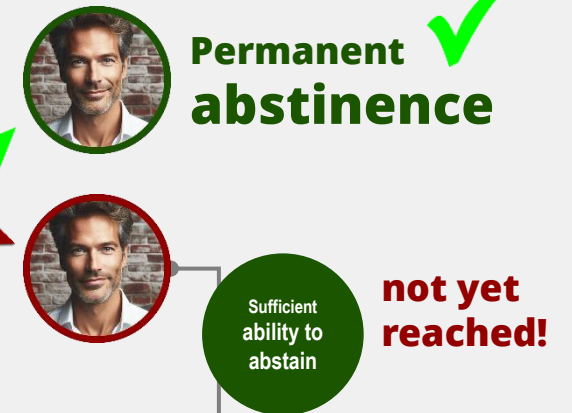
Self-confidence: Smoke-free is a gain in quality of life

- 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

12. Smoke "less" first! with CiQuit - High success rates

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

Ziel **> 80%**

Ability to abstain

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

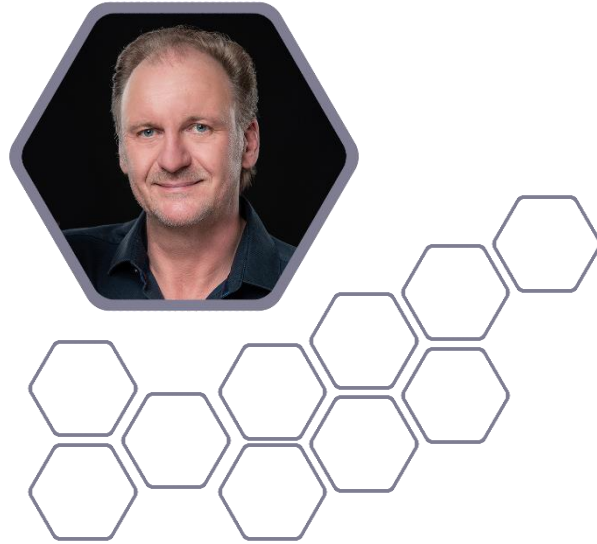
At best 5 or less cigarettes a day

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)**

Change mental attitude:

Building "**anticipation**" for a smoke-free life!

Thank you very much



Contact

Andreas Unsicker

E-Mail: unsicker@luna-medical.de

Mobil: + 49 172 533 42 92

www.luna-medical.com

LUNA medical GmbH

Yorckstr. 6

93049 Regensburg, Germany

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.