CiQuit®

The Crowded Market-Quit Smoking "Now"

Taking Germany as an example.





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Tobacco consumption

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

Further PDF documents

World Health Organization

- 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"!

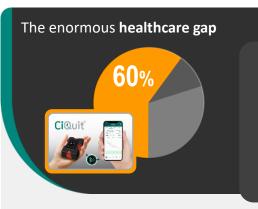
Anny offers of help = Crowded market

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!



i ii

• Significant reduction

quitting smoking

• Improvement of life quality

Building motivation and

optimal preparation for

Several goals:

as a smoker

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!



European Network for Smoking and Tobacco Prevention

The reduction of smoking ...

... increases the likelihood of a future attempt to stop smoking.

... strengthens the patient's confidence in their ability to stop smoking completely and increase the number of quit attempts per year.

... reduces at least some of the risks associated with smoking.¹

"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

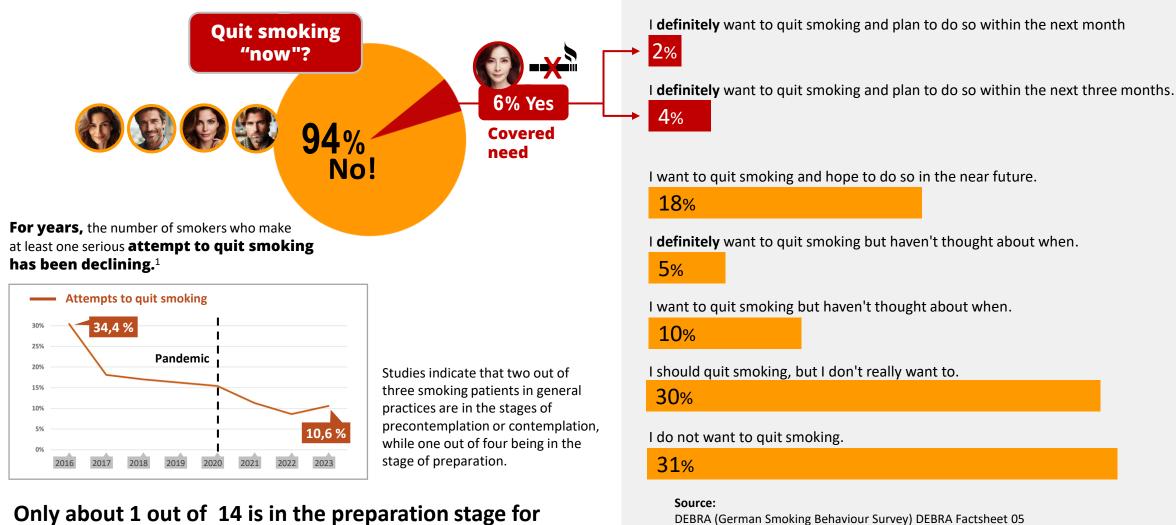
Prof. Dr. Joachim Körkel u. Matthias Nanz, The paradigm of open-ended addiction work, 2016,

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2. Quit smoking "now"! - A snapshot

quitting smoking.²

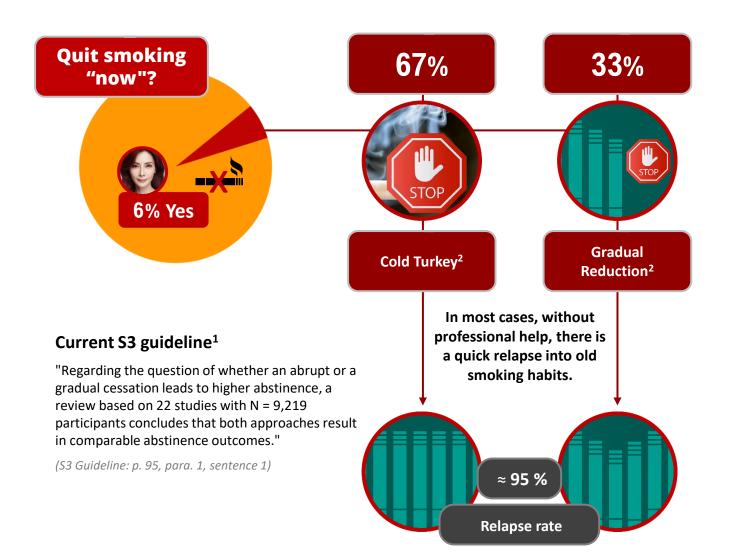
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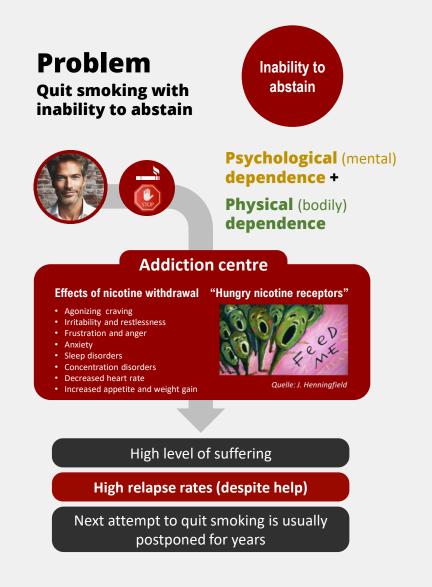


DEBRA (German Smoking Behaviour Survey) DEBRA Factsheet 05 The Motivation to Quit Smoking Scale (MRS) with survey3 ³



3. Quit smoking "now"! - Methods of realisation







Quelle: https://register.awmf.org/assets/guidelines/076-0061_S3_Rauchen-_Tabakabhaengigkeit-Screening-Diagnostik-Behandlung_2021-03.pdf
 Quelle: https://www.aerzteblatt.de/archiv/211741/Rauchstoppversuche-und-genutzte-Entwoehnungsmethoden

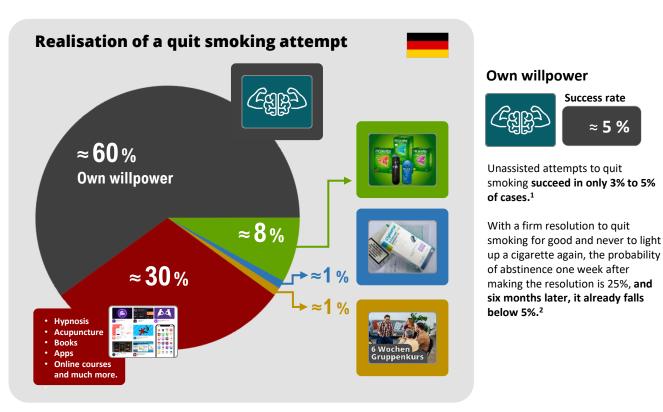
4. Relying only on willpower - The wrong strategy

Problem

_ U N

Α

Attempts to quit smoking on one's own willpower despite a very low success rate, as many smokers overestimate their ability to guit smoking without support. This overestimation leads to the avoidance of evidence-based assistance, in the hope of being successful through their own willpower. Evidence-based assistance, at least, increases the chances of success.



Important! S3 guideline³

"Unlike many other health interventions, individuals seeking to guit smoking are typically not advised by a medical consultant on the most effective method based on scientific evidence. Instead, those affected often inform themselves in a loosely regulated market of tobacco cessation offerings."

Nicotine

Success rate

≈ 5 %

Replacement Therapy



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

Do nicotine replacement products help to quit smoking? ⁵

Nicotine replacement products

16 out of 100 people who used a nicotine replacement product no longer smoked.* *(After 6 or 12 month)

Quelle: Hartmann-Boyce et al. (2018)

Placebo products

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



1) Source: https://www.aerzteblatt.de/pdf.asp?id=221166 | Versuch und Scheitern

2) Source : https://www.dhs.de/fileadmin/user_upload/pdf/Broschueren/Suchtmedizinische_Reihe_Tabakabha%CC%88ngigkeit_BFREI.pdf 3) Source : https://register.awmf.org/assets/guidelines/076-006l S3 Rauchen- Tabakabhaengigkeit-Screening-Diagnostik-Behandlung 2021-03.pdf 4) Source: https://www.cochrane.de/news/ein-neuer-cochrane-review-untersucht-die-wirksamkeit-von-unterschiedlichen 5) Source: https://www.stiftung-gesundheitswissen.de/wissen/rauchentwoehnung/koennen-nikotinpflaster-und-co-bei-der rauchentwoehnung-helfen

Non-smoking courses are very rarely utilized!¹

	Benefits from statutory health insurance						
	Individual behavioural prevention						
Spitzenverband	2017	2018	2019	2020	2021	2022	
Total course participation	1.675.008	1.685.490	1.805.889	1.157.305	796.595	1.294.193	
Example field of action: Movement	1.159.826	1.155.187	1.223.676	732.653	466.144	769.853	
Share in %	69,24%	68,54%	67,76%	63,31%	58,52%	59,49%	
Example field of action: Stress management	438.854	462.829	514.285	363.332	275.593	452.486	
Share in %	26,20%	27,46%	28,48%	31,39%	34,60%	34,96%	
Example field of action: Addictive drugs	11.647	10.675	8.552	5.362	4.297	6.351	
Share in %	0,70%	0,63%	0,47%	0,46%	0,54%	0,49%	
Promotion of non-smoking	10.630	9.360	7.609	5.043	3.746	5.989	
Share in %	0,63%	0,56%	0,42%	0,44%	0,47%	0,46%	

1) Source:

https://gkvspitzenverband.de/krankenversicherung/praevention _selbsthilfe_beratung/praevention_und_bgf/praeven tionsbericht/praeventionsbericht.jsp

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



≈ **35** %

Non-smoking courses

In clinical practice, professional tobacco cessation treatments report 12-month abstinence rates between 25% and 40%.¹⁰ Intensive interventions with multiple contacts before and after the quit date achieve higher abstinence rates.¹¹

Source: https://www.dhs.de/fileadmin/user_upload/pdf/Broschueren/Suchtmedizinische_Reihe_Tabakabha%CC%88ngigkeit_BFREI.pdf
 Source: https://www.aerzteblatt.de/pdf.asp?id=221166 | Trial and failure

Source: https://register.awmf.org/assets/guidelines/076-006I_S3_Rauchen-_Tabakabhaengigkeit-Screening-Diagnostik-Behandlung_2021-03.pdf
 Source: https://drks.de/search/de/trial/DRKS00025933 | Basic results | Conclusions

6) Source: https://www.cochrane.de/news/ein-neuer-cochrane-review-untersucht-die-wirksamkeit-von-unterschiedlichen

7) Source: https://www.stiftung-gesundheitswissen.de/wissen/rauchentwoehnung/koennen-nikotinpflaster-und-co-bei-der-rauchentwoehnung-helfen 8) Source: https://www.stiftung-gesundheitswissen.de/wissen/rauchentwoehnung/kann-vareniclin-bei-der-rauchentwoehnung-helfen



Excursus

Success rates in tobacco cessation



With a firm resolution to quit smoking for good and never to light up a cigarette again, the probability of abstinence one week after making the resolution is 25%, and six months later, it already falls below 5%.² Unassisted attempts to quit smoking succeed in only 3% to 5% of cases.³



≈ **10** %

≈ 5 %

Apps and Online programs

Mobile self-help programs, S3 guideline: This Risk Ratio (RR) means that on average, 5.6% in the control groups and 9.3% in the intervention groups have successfully quit smoking.⁴ NichtraucherHelden-App (DiGA), study result: The NichtraucherHelden-App doubles the abstinence rate.⁵



Nicotine Replacement Therapy

63 studies with 41,509 participants: 17% who combined a patch with another intervention were able to quit, compared with 14% who used a single form of Nicotine Replacement Therapy (NRT).⁶ 16%, die NET nutzten, rauchten nicht mehr. 11%, die ein Placebo verwendeten, rauchten nicht mehr.⁷



≈ 25 %

≈ 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

Source: https://www.stiftung-gesundheitswissen.de/wissen/rauchentwoehnung/kann-bupropion-bei-der-rauchentwoehnung-helfen
 Source: https://register.awmf.org/assets/guidelines/076-006L_S3_Rauchen-_Tabakabhaengigkeit-Screening-Diagnostik-Behandlung_2021-03.pdf
 Source: https://www.dhs.de/fileadmin/user_upload/pdf/Broschueren/Suchtmedizinische_Reihe_Tabakabha%CC%88ngigkeit_BFREI.pdf

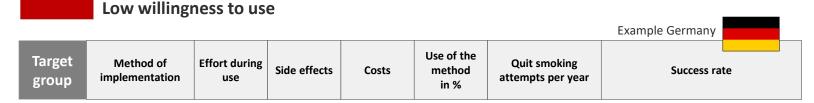
6. Barriers to utilizing offers of help • Effort

High willingness to use

Side effects

Costs •

CiQuit: No or only low barriers to utilisation



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

	Own willpower	No	No	No	60 %	1.200.000	≈ 5 %	One goal:
10.0/	NRT Nicotine replacement therapy	No	Low	High ≈ 150 - 300 €	8 %	160.000	≈ 15 %	Quit smoking
10 %	Medication e.g. Zyban, Champix	No	High	High ≈ 150 - 300 €	1%	20.000	≈ 2 5 %	YES or
	Courses with Gruppenkurs presence	High	No	High ≈ 150 - 250 €	1%	20.000	≈ 3 5 %	NO

Several goals: **Uncovered need - Smoke "less" first!** Significant reduction Medium No No • Improvement of life = high willingness 60 % quality as a smoker to use No¹ No No **Building motivation and** optimal preparation for quitting smoking

1) Cost coverage by health insurance funds as DiGA = digital health application according to MDR I

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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 quideline: 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.



Cost coverage NO

Using NRT during an attempt to quit smoking



England Cost coverage **YES** 48%

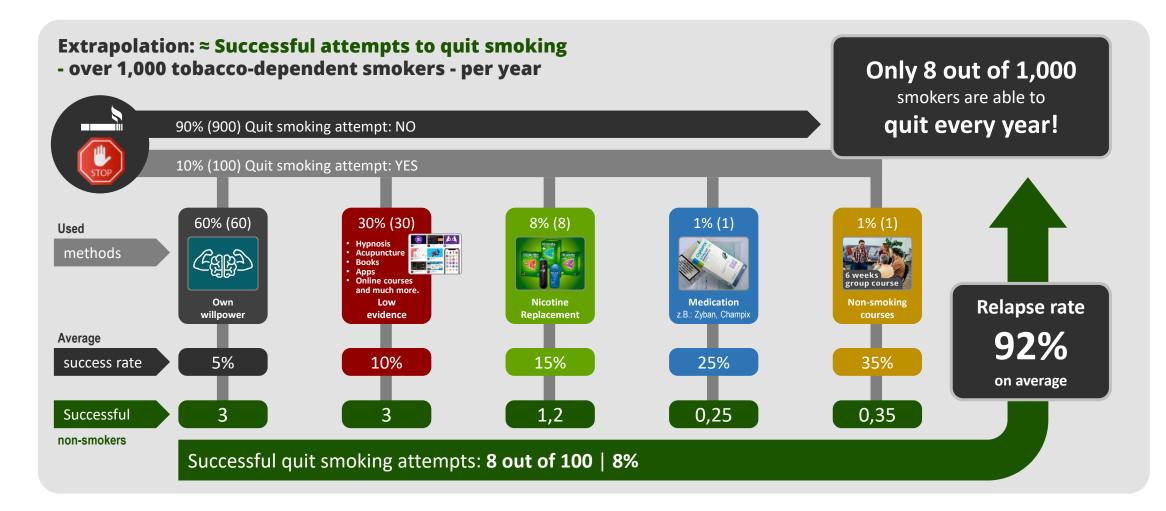
Using NRT during an attempt to quit smoking

1) Source: https://register.awmf.org/assets/guidelines/076-006l S3 Rauchen- Tabakabhaengigkeit-Screening-Diagnostik-Behandlung 2021-03.pdf 2) Source: https://www.aerzteblatt.de/archiv/211741/Rauchstoppyersuche-und-genutzte-Entwoehnungsmethoder

Goal: Inability to abstain > 80%

7. High relapse rates despite many offers of help

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



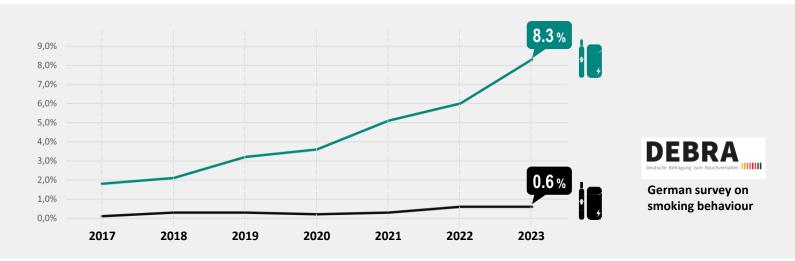


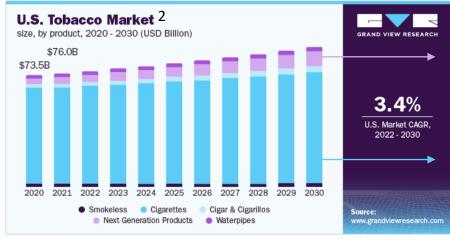
8. Tobacco heaters (IQOS & Co.) - Germany as an example

In 2023

LUNA

- 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 ecigarettes and heaters, including flavour bans, can reduce their appeal.
- 6. Taste and Sensory Experience: Many smokers prefer the taste and smoking experience of traditional cigarettes over the perceived artificial flavours of e-cigarettes.
- 7. Doubts about Cessation Effectiveness: Uncertainties about the efficacy of these products as smoking cessation aids lead some smokers to revert to cigarettes.

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

9. CiQuit - Rubicon model: The quick decision to use

This is what the medical profession says!¹

Ineffectiveness

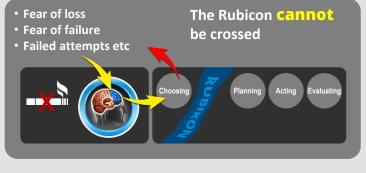
"Patients are usually only slightly motivated or not motivated at all to quit smoking."

Too time-consuming

" Initiating tobacco cessation is cumbersome and doomed to fail in most cases."

Quit smoking "now"! Fear of losing something "precious"!

- Long decision-making process
- High persuasion effort



No, not now!

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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



Motivational psychology

Rubicon model

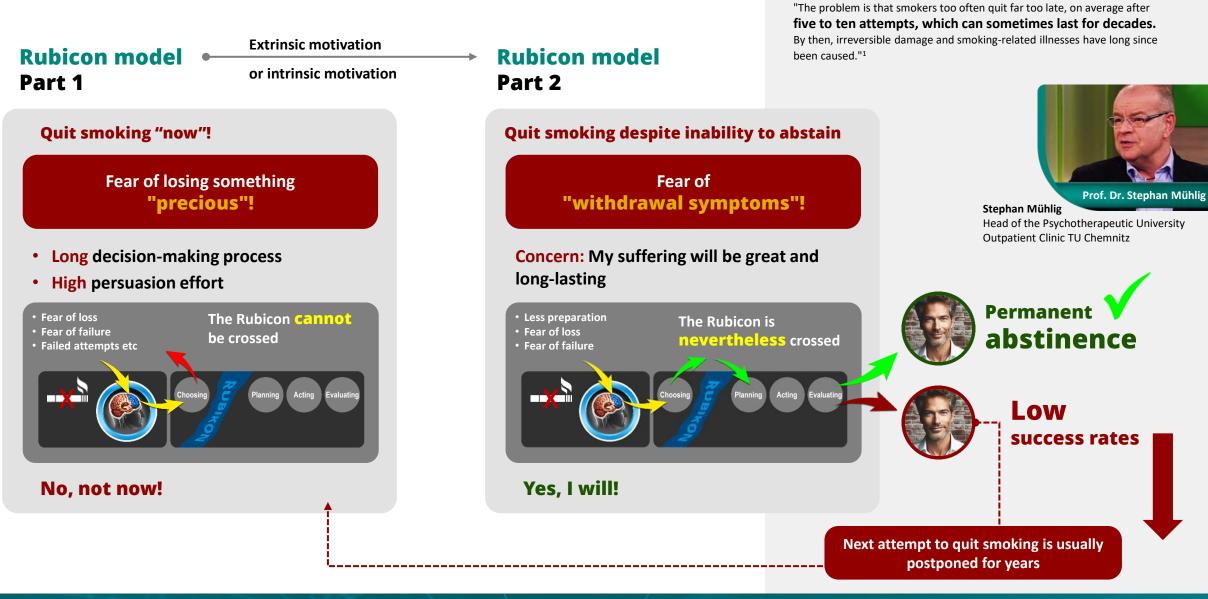
- It is important that wishes are transformed into concrete goals.
- This is known as crossing the Rubicon.

A clear goal ends choosing and sets the organism to "GO!"

- Choosing Reduce your smoking? Simple decision = Yes, I will!
- Planning The CiQuit therapy takes over!
- Acting The CiQuit therapy will be realised!
- Evaluating Subgoals successfully realised? Maintaining motivation, as the partial successes adapt to the patient's progress.

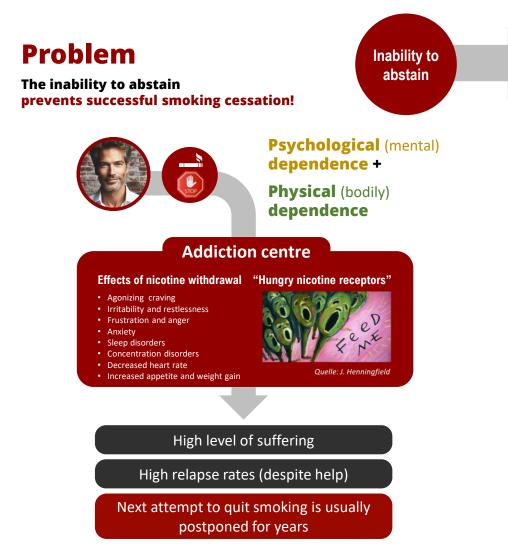
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10. Quit smoking "now"! - In the context of the Rubicon model

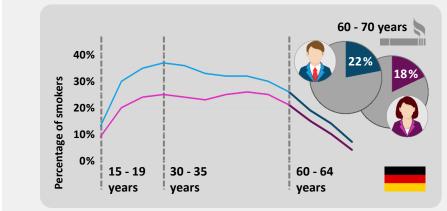




11. Quit smoking "now"! - Low success rates



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



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)

Quelle: Hartmann-Boyce et al. (2018)

Placebo product

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



Quit smoking attempt - method and success rate:

Only willpower



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



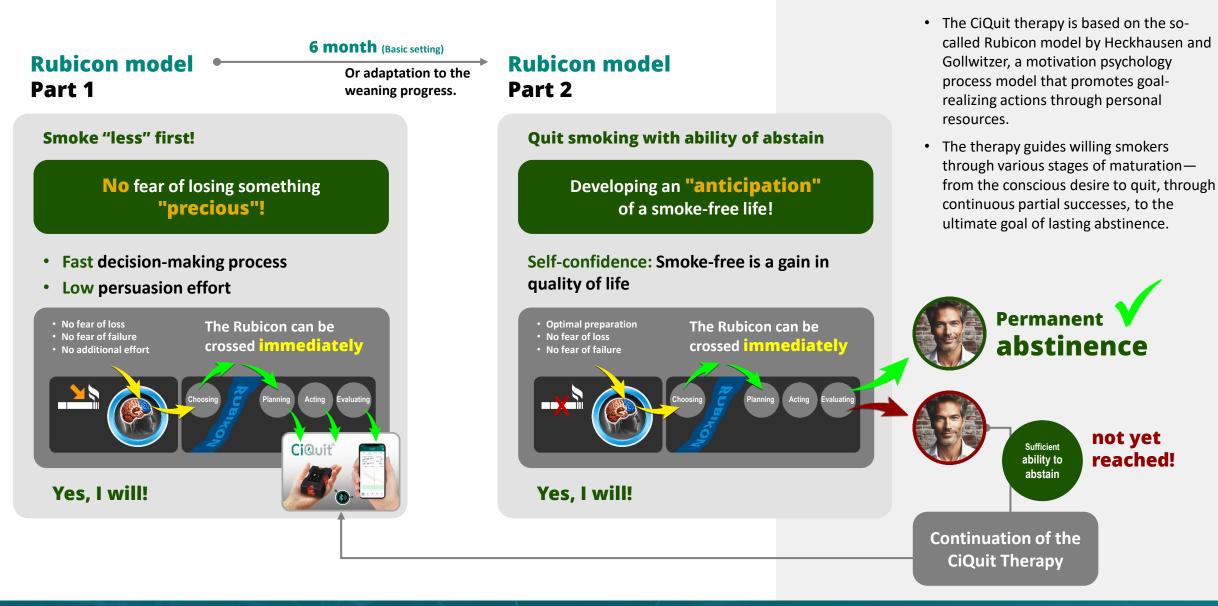
63 studies with 41,509 participants: 17% who combined a patch with another intervention were able to quit, compared with 14% who used a single form of nicotine replacement therapy (NRT).⁴

Further methods and success rates: See Appendix 1 to 3



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-nikotinpflaster-und-co-bei-der-rauchentwoehnung-helfen 4) Source: https://www.cochrane.de/news/ein-neuer-cochrane-review-untersucht-die-wirksamkeit-von-unterschiedlichen

12. Smoke "less" first! with CiQuit - In the context of the Rubicon model



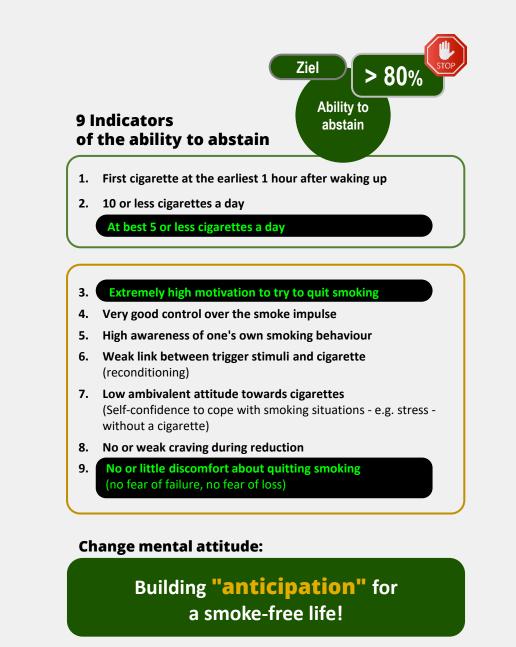
14

not yet

reached!

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







14. The unfulfilled need

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

That's what science says!

1.000

900

400

200

University of Bath²

the traditional

2015

"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 guitting immediately, as well as smokers who currently do not wish to attempt guitting.¹

to substitute products or quitting smoking immediately 30% No change in smoking behaviour World Health Organization Around 1.3 billion tobacco consumers 60% Global sales of tobacco products in US\$ billion, forecast to 2025 Smoke "less" tobacco cigarettes \$780 Tobacco heater first! Over 1 billion people smoke Smokeless tobacco E-cigarettes **CiQuit** tobacco cigarette Cigars, cigarillos, tobacco Tobacco cigarettes 2020 2025 Enormous **Uncovered** need healthcare gap No need **Covered** need

Competitors focus on switching

10%





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

- Source : https://www.verifiedmarketreports.com/product/e-cigarette-and-vaping-market/
- 16 Source : https://www.researchandmarkets.com/reports/4968933/global-smoking-cessation-and-nicotine-de-addiction

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.

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