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„Evaluation der Rauchfrei-Hotline der Bundeszentrale für gesundheitliche Aufklärung. Eine randomisiert kontrollierte Studie“

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Simone Delle
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Eidesstattliche Versicherung

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Ich erkläre hiermit an Eides statt, dass ich die vorliegende Dissertation mit dem Titel:

„Evaluation der Rauchfrei-Hotline der Bundeszentrale für gesundheitliche Aufklärung. Eine randomisiert kontrollierte Studie“

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München, 21.03.2025 Simone Delle

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Inhaltsverzeichnis

Abkürzungsverzeichnis

AWMF: Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften e.V.

BZgA: Bundeszentrale für gesundheitliche Aufklärung (Federal Centre for Health Education)

DALY: Disability-adjusted life years

DHS: Deutsche Hauptstelle für Suchfragen

FTCD: Fagerström Test für Zigarettenabhängigkeit (Fagerström Test for Cigarette Dependence)

FTND: Fagerström Test für Nikotinabhängigkeit (Fagerström Test for Nicotine Dependence)

HNB: Heat-not-burn product

ICD-10: Internationale Klassifikation von Krankheiten, 10. Revision (International Statistical Classification of Diseases and Related Health Problems, 10th revision)

IFT: Institut für Therapieforschung

NRT: Nikotinersatztherapie (nicotine replacement therapy)

OR: Odds ratio

SRNT: Society for Research on Nicotine and Tobacco

S3-Leitline Tabakabhängigkeit:
S3-Leitlinie "Rauchen und Tabakabhängigkeit:
Screening, Diagnostik und Behandlung"

WHO: Weltgesundheitsorganisation (World Health Organization)

WHO FCTC: Rahmenübereinkommen der Weltgesundheitsorganisation zur Eindämmung des Tabakgebrauchs (WHO Framework Convention on Tobacco Control)

Publikationsliste

Publikationen als Bestandteil der vorliegenden Dissertation:

Paper I:

Delle, S., Kraus, L., Maspero, S., Pogarell, O., Hoch, E., & Lochbühler, K. (2022). Effectiveness of the national German quitline for smoking cessation: study protocol of a randomized controlled trial. *BMC Public Health, 22*(1), 1386. doi: 10.1186/s12889-022-13742-4

Paper II:

Maspero, S., Delle, S., Kraus, L., Pogarell, O., Hoch, E., Bachner, J., & Lochbühler, K. (2024). Short-term effectiveness of the national German quitline for smoking cessation: results of a randomized controlled trial. *BMC Public Health, 24*, 588. doi:10.1186/s12889-024-18104-w

Paper III:

Delle, S., Kraus, L., Maspero, S., Pogarell, O., Hoch, E., & Lochbühler, K. (2024). Long-term effectiveness of a quitline for smoking cessation: results of a randomized controlled trial. *European Addiction Research,* 2024. doi:10.1159/000541682

Weitere Publikationen:

Delle, S., Seitz, N.-N., Atzendorf, J., Mühlig, S., & Kraus, L. (2021). Motives for not drinking alcohol: why adults in late middle age abstain. *Addiction Research and Theory*, 1-8. doi: 10.1080/16066359.2021.1954167

Atzendorf, J., Aschenbrenner, A. B., Gomes de Matos, E., Kraus, L., Delle, S., & Piontek, D. (2018). E-Zigaretten: Einschätzung von Gesundheitsgefahren und Nutzung zur Tabakentwöhnung. *Bundesgesundheitsblatt, 61*, 1415–1421. doi: 10.1007/s00103-018-2822-z

Vorträge:

Delle, S., Kraus, L., Maspero, S., Pogarell, O., Hoch, E., & Lochbühler, K. (2023-12-06). Evaluation der Telefonberatung zur Rauchentwöhnung der Bundeszentrale für gesundheitliche Aufklärung (BZgA). Vortrag, 21. Deutsche Konferenz für Tabakkontrolle, Heidelberg.

Delle, S., Kraus, L., Maspero, S., Pogarell, O., Hoch, E., & Lochbühler, K. (2023-05-13). Effectiveness of the national German quitline for smoking cessation: preliminary results of a randomized controlled trial (A.018). Presentation, 26th International Conference of European Association of Substance Abuse Research EASAR, Kaunas, Lithuania.

Delle, S., Kraus, L., Maspero, S., Pogarell, O., Hoch, E., & Lochbühler, K. (2022-05-12). Effectiveness of the German smokers quitline: study protocol of a randomized controlled trial. Presentation, 25th European Association of Substance Abuse Research (EASAR) Conference, Gibraltar.

Delle, S., Kraus, L., Seitz, N.-N., Atzendorf, J., & Mühlig, S. (2021-09-13). Motive für den Verzicht auf Alkohol: Warum ältere Erwachsene abstinent sind (S-14-004). Vortrag, Deutscher Suchtkongress 2021, Berlin.

1. Beitrag zu den Publikationen

1.1 Beitrag zu Paper I

Die Autorin der vorliegenden Dissertation (Simone Delle) hat wesentlich zur Konzeption sowie der Studienfrage des Papers beigetragen. Sie schrieb das Originalmanuskript sowie die endgültige Fassung der veröffentlichten Version und begleitete den Publikationsprozess federführend von der Einreichung des Manuskripts im Journal über den Reviewprozess bis hin zur Bearbeitung der Druckfahnen.

1.2 Beitrag zu Paper II

Die Autorin der vorliegenden Dissertation (Simone Delle) hat als Ko-Autorin des Paper II wesentlich zur Konzeption sowie der Studienfrage beigetragen. Sie führte die statistischen Analysen gemeinsam mit der Autorin des Paper II (Simona Maspero) durch und unterstützte bei der Interpretation der Ergebnisse. Sie überarbeitete das Originalmanuskript und unterstützte im Reviewprozess.

1.3 Beitrag zu Paper III

Die Autorin der vorliegenden Dissertation (Simone Delle) hat wesentlich zur Konzeption sowie der Studienfrage des Papers beigetragen. Sie bereitete den Datensatz für sämtliche Analysen vor, führte die statistischen Analysen durch und interpretierte die Ergebnisse. Sie schrieb das Originalmanuskript sowie die endgültige Fassung der veröffentlichten Version und begleitete den Publikationsprozess federführend von der Einreichung des Manuskripts im Journal über den Reviewprozess bis hin zur Bearbeitung der Druckfahnen.

2. Einleitung

*"Das Rauchen ist ein absurder Zeitvertreib. Es nimmt Zeit weg, statt sie zu füllen; es verschwendet Geld, statt es zu sparen; und es tötet dich, statt dich zu erfreuen" (*Romain Rolland).

2.1 Prävalenz des Rauchens

In Deutschland ist der Konsum von Tabakprodukten noch immer weit verbreitet. In der 18- bis 59-jährigen Bevölkerung in Deutschland lag die 30-Tage-Prävalenz des Konsums konventioneller Tabakprodukte im Jahr 2021 bei 22,7 % (11,6 Mio. Rauchende) und 13,7 % (7,0 Mio. Rauchende) konsumierten täglich (Rauschert et al., 2022). Von den Tabakkonsumierenden gaben 21,0 % (2,4 Mio.) an, mindestens 20 Zigaretten pro Tag zu rauchen. Wasserpfeifenkonsum wurde von 4,1 % (2,1 Mio. Personen), E-Zigarettenkonsum von 4,3 % (2,2 Mio. Personen) und die Verwendung von Tabakerhitzern von 1,3 % (665.000 Personen) angegeben (30-Tage-Prävalenz) (Rauschert et al., 2022).

2.2 Auswirkungen des Rauchens

2.2.1 Gesundheitliche Auswirkungen

Rauchen ist weiterhin die Hauptursache für vermeidbare Krankheiten, Beeinträchtigungen und Todesfälle. So starben im Jahr 2019 weltweit 7,69 Millionen Menschen an den Folgen von Tabakkonsum und die Krankheitslast kann mit 200 Millionen „disability-adjusted life years“ (DALYs) beziffert werden (GBD 2019 Cancer Risk Factors Collaborators, 2022). Rauchende erkranken dabei vermehrt an z. B. Herz-Kreislauf-, Atemwegs- und Krebserkrankungen (Deutsche Hauptstelle für Suchtfragen e.V. (DHS), 2024). Die durch das Rauchen verursachten Krebsfälle wurden im Jahr 2018

auf 85.072 geschätzt, was 19 % aller Krebsneuerkrankungen ausmachte (Mons et al., 2018). Insgesamt wurden dabei über 80 % aller Lungenkrebsfälle durch den Konsum von Tabak bedingt. Zudem schädigt Tabakkonsum das Immunsystem, den Stoffwechsel, das Skelett, den Zahnhalteapparat, die Augen und die Fruchtbarkeit (Deutsche Hauptstelle für Suchtfragen e.V. (DHS), 2024).

2.2.2 Tabakabhängigkeit

In Deutschland weisen 4,0 Millionen Rauchende Anzeichen für eine Tabakabhängigkeit auf (Rauschert et al., 2022). Diese setzt sich aus einer körperlichen und psychischen Komponente zusammen, welche ähnlich stark ausgeprägt sind (Nutt et al., 2007) und in der S3-Leitlinie "Rauchen und Tabakabhängigkeit: Screening, Diagnostik und Behandlung" (S3-Leitline Tabakabhängigkeit) (Batra et al., 2021) wie folgt definiert werden:

> Körperliche Abhängigkeit erklärt das Auftreten eines Entzugssyndroms. Der Zustand tritt bei Absetzen oder Reduktion des Substanzkonsums auf und geht mit substanzspezifischen psychovegetativen Symptomen einher […]. Die psychische Abhängigkeit wird häufig als Ausdruck der Kontrollminderung bzw. des Kontrollverlustes, des zwanghaften Konsums und eines starken Cravings beschrieben. Psychische Abhängigkeit geht einher mit der individuellen funktionellen Bedeutung des Konsums […]. (Batra et al., 2021, S. 38)

Die Diagnostik einer Abhängigkeit (F17.2) kann nach der Internationalen Klassifikation von Krankheiten (ICD-10) der Weltgesundheitsorganisation (WHO) erfolgen (Dilling & Freyberger, 2019). Dafür müssen drei der nachfolgenden Kriterien innerhalb eines Zeitraumes von einem Jahr wiederholt oder während eines Zeitraumes von einem Monat durchgängig erfüllt sein:

1. Starker Wunsch oder Zwang, psychotrope Substanzen zu konsumieren.
2. Verminderte Kontrollfähigkeit bzgl. des Beginns, der Beendigung und der Menge des Konsums.

3. Körperliches Entzugssyndrom bei Beendigung bzw. Reduktion des Konsums.
4. Nachweis einer Toleranz: Um die ursprünglich durch niedrigere Dosen erreichten Wirkungen der Substanz hervorzurufen, sind zunehmend höhere Dosen erforderlich.
5. Fortschreitende Vernachlässigung anderer Vergnügungen oder Interessen zugunsten des Substanzkonsums, erhöhter Zeitaufwand, um die Substanz zu beschaffen, zu konsumieren oder sich von den Folgen zu erholen.
6. Anhaltender Substanzkonsum trotz des Nachweises eindeutiger schädlicher Folgen körperlicher oder psychischer Art, wenn der Konsument sich über Art und Ausmaß der schädlichen Folgen im Klaren war oder zumindest davon auszugehen ist.

Der Grad der Tabakabhängigkeit kann mit dem Fagerström Test für Zigarettenabhängigkeit (FTCD), vormals Fagerström Test für Nikotinabhängigkeit (FTND), klassifiziert werden (Fagerström, 2012; Heatherton et al., 1991). Der FTCD ist der am häufigsten verwendete Selbstbeurteilungs-Test und besteht aus sechs Fragen welche z. B. neben der Anzahl oder dem Zeitpunkt der gerauchten Zigaretten auch psychische Kriterien abfragt (z. B. „*Finden Sie es schwierig, an Orten, wo das Rauchen verboten ist (z. B. in der Kirche, in der Bibliothek, im Kino usw.) darauf zu verzichten*?“) (Heatherton et al., 1991).

2.2.3 Ökonomische Auswirkungen

Die gesundheitlichen Folgen des Tabakkonsums belasten das Gesundheitswesen und die Volkswirtschaft erheblich. Die Gesamtkosten des Tabakkonsums in Deutschland beliefen sich in 2018 auf mindestens 97,24 Milliarden Euro (Effertz, 2019). Diese konservative Schätzung umfasst direkte und indirekte Kosten, Schmerz und Leid durch Tabakkonsum lässt sich zusätzlich quantifizieren. Direkte Kosten entstehen z. B. durch medizinische Versorgung und berufliche Rehabilitation, während indirekte Kosten durch Ressourcenverluste in Folge z. B. von Arbeitsunfähigkeit und Tod entstehen. In

Deutschland beliefen sich in 2018 die jährlichen direkten Kosten auf 30,32 Milliarden Euro und die indirekten Kosten auf 66,92 Milliarden Euro (Effertz, 2019). Insgesamt übersteigen die Kosten des Tabakkonsums die Einnahmen aus Tabaksteuern um ein Vielfaches (Deutsche Hauptstelle für Suchtfragen e.V. (DHS), 2024).

2.3 Rauchentwöhnung

Die Rauchentwöhnung spielt eine entscheidende Rolle bei der Reduzierung des Tabakkonsums und der Verbesserung der öffentlichen Gesundheit. Da Tabakkonsum in allen Formen (Rauchen, Schnupfen, Kauen) gesundheitsschädlich ist, also ein unschädlicher Gebrauch nicht möglich ist, muss deshalb nicht nur den nach der ICD-10 Diagnostik (Dilling & Freyberger, 2019) behandlungsbedürftigen Rauchenden, sondern letztlich allen Aufhörwilligen ein passendes Unterstützungsangebot gemacht werden können, wenn sie den Rauchstopp nicht alleine schaffen (Batra et al., 2021). Dies gilt umso mehr, da viele der gesundheitlichen Risiken, die durch das Rauchen entstehen, durch einen Rauchstopp vermindert oder sogar komplett reversibel sind (Schaller et al., 2020) .

In Deutschland bietet die S3-Leitline Tabakabhängigkeit evidenzbasierte Empfehlungen für den Umgang mit Rauchen und Tabakabhängigkeit (Batra et al., 2021), welche von Fachexperten und -expertinnen der Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften e.V. (AWMF) entwickelt wurde. Hierzu gehören eine medikamentöse Behandlung in Form von einer Nikotinersatztherapie (NRT) oder anderen Arzneimitteln, psychotherapeutische Interventionen sowie Motivationsbehandlungen und Kurzinterventionen. E-Zigaretten wurden in der S3-Leitline Tabakabhängigkeit bislang auf Grund fehlender Evidenz nicht zur Unterstützung eines Rauchstopps empfohlen, werden nachfolgend jedoch ebenfalls beschrieben, da sie

sehr häufig bei einem Rauchstopp herangezogen werden (Kotz et al., 2018) und sich die Studienlage seit Veröffentlichung der Leitlinie verbessert hat (s. u.).

2.3.1 Medikamentöse Behandlung

Die medikamentöse Behandlung unterstützt aufhörwillige Rauchende durch eine Linderung der Entzugssytomatik nach dem Rauchstopp und kann zur Stabilisierung der Abstinenz beitragen (Batra et al., 2021). Die Gabe des Arzneistoffes Nikotin in Form der NRT (Nikotinkaugummi, Nikotininhaler, Nikotinlutschtablette, Nikotinnasalspray, Nikotinmundspray und Nikotinpflaster) ist hierbei erste Wahl, wobei die Dosis individuell zu bestimmen ist und ggf. zwei Präparate kombiniert werden sollten (Batra et al., 2021). Die Wirksamkeit von NRT zur Rauchentwöhnung ist hinreichend belegt (Livingstone-Banks et al., 2022). Sollte die Tabakentwöhnung mit NRT nicht wirksam sein, so kann vorrangig das Antidepressivum Bupropion, sowie der partielle Nikotinrezeptoragonist Vareniclin eingesetzt werden (Batra et al., 2021). Deren Wirksamkeit zur Tabakentwöhnung und Unbedenklichkeit hinsichtlich unerwünschter psychiatrischer und kardiovaskulärer Nebenwirkungen ist hinreichend dokumentiert (Anthenelli et al., 2016; Benowitz et al., 2018). Eine aktuelle Meta-Analyse von Lindson et al. (2023) zeigt, dass zwei NRTs, welche kombiniert eingesetzt werden, höhere Effekte auf die Abstinenz haben als die Verwendung eines NRT alleine oder der medikamentösen Begleitung mit Vareniclin oder Bubropion. Die Behandlung mit weiteren Medikamenten (Cytisin, Clonidin) sind unter spezifischen Umständen möglich (Batra et al., 2021). In jedem Fall soll eine medikamentöse Behandlung des Rauchstopps durch begleitende verhaltenstherapeutsche Interventionen (s. Kap. 2.3.2) unterstützt werden, da dies die Rauchstoppquote erhöht (Hartmann-Boyce et al., 2019).

2.3.2 Psychotherapeutische Interventionen

Die S3-Leitline Tabakabhängigkeit empfiehlt eine Vielzahl verhaltenstherapeutischer Einzel- und Gruppeninterventionen, welche in der medizinischen, psychotherapeutischen und psychosozialen Gesundheitsversorgung angeboten werden sollen (Batra et al., 2021). Dazu gehören Verhaltenstherapieprogramme, die individuell angepasst werden können, um die Bedürfnisse und Präferenzen der Rauchenden zu berücksichtigen. Typische Interventionen umfassen „mehrere Komponenten (insbes. Psychoedukation, Motivationsstärkung, Maßnahmen zur kurzfristigen Rückfallprophylaxe, Interventionen zur Stärkung der Selbstwirksamkeit, alltagspraktische Beratung mit konkreten Verhaltensinstruktionen und praktischen Bewältigungsstrategien (Problemlöse- und Fertigkeitentraining, Stressmanagement)“ (Batra et al., 2021, S. 83). Für die Wirksamkeit verhaltenstherapeutischer Interventionen zur Tabakentwöhnung gibt es hinreichend Evidenz (Stead et al., 2017).

2.3.3 Motivationsbehandlung und Kurzinterventionen

Motivationsbehandlungen und Kurzinterventionen zielen darauf ab, eine große Anzahl von Rauchenden mit weniger aufwändigen und kostengünstigeren Ansätzen als intensive medikamentöse oder psychotherapeutische Behandlungen zu erreichen. Es wird empfohlen, sie von Gesundheitsfachkräften persönlich (direkt oder telefonisch) anzubieten oder sie automatisiert über verschiedene Medien wie Selbsthilfematerialien, das Internet oder Mobiltelefone bereitzustellen (Batra et al., 2021). Deren Evidenz im Vergleich zu keiner Behandlung ist vielfach belegt (Lancaster & Stead, 2005; Livingstone-Banks et al., 2019; Stead et al., 2013). Die Wirksamkeit hängt jedoch auch maßgeblich von der Qualität der Behandlung ab, weswegen ein Programm empfohlen wird, „wenn es evidenzbasierte Therapieinhalte der Tabakentwöhnungsbehandlung beinhaltet oder wenn es sich als Gesamtprogramm als effektiv erwiesen hat“ (Batra et al.,

2021, S. 54). Die S3-Leitline Tabakabhängigkeit (Batra et al., 2021) empfiehlt für das Erreichen eines erfolgreichen Rauchstopps auch die Inanspruchnahme der Rauchentwöhnungshotline der Bundeszentrale für Gesundheitliche Aufklärung (BZgA), welche auf evidenzbasierten Inhalten aufbaut (Lindinger et al., 2012). Die generelle Wirksamkeit von Quitlines konnte in einem Review nachgewiesen werden (Matkin et al., 2019).

2.3.4 E-Zigaretten

In der aktuellen S3-Leitline Tabakabhängigkeit wird auf Grund einer unzureichenden Evidenzlage empfohlen, E-Zigaretten weder zur Reduzierung des Zigarettenkonsums noch zur Unterstützung beim Rauchstopp einzusetzen und von ihrer Verwendung abzuraten (Batra et al., 2021). Eine aktuelle Meta-Analyse mit sieben inkludierten Studien und 2.544 Teilnehmern von Lindson et al. (2024) zeigt jedoch, dass nikotinhaltige E-Zigaretten im Vergleich zu NRT die Erfolgsquoten beim Rauchstopp statistisch signifikant erhöhen (RR 1,59, 95 %-KI [1,29; 1,93]). E-Zigaretten haben das Potenzial, Erwachsene beim Rauchstopp zu unterstützen oder die schädlichen Auswirkungen von Tabakrauchen zu vermindern und sollten deshalb in Zukunft für die Tabakentwöhnung in Betracht gezogen werden (Balfour et al., 2021).

2.4 Tabakkontrolle

Die Entwicklung und Bereitstellung von bundesweit verfügbaren und effektiven Rauchstoppmethoden steht im Mittelpunkt einer effektiven Tabakkontrollpolitik (Borland et al., 2001). Um die Abnahme der Tabakprävalenz in der Bevölkerung weiter zu beschleunigen, werden innovative Ansätze benötigt, um Rauchende zu erreichen, um Rauchstoppversuche zu ermutigen und Rauchende zu behandeln (Gilbert & Sutton, 2006; Graham et al., 2011). Im internationalen Kontext wurden Bemühungen zur Bekämpfung

des Tabakkonsums durch das Rahmenübereinkommen der Weltgesundheitsorganisation zur Eindämmung des Tabakgebrauchs (WHO FCTC) verstärkt (World Health Organization, 2003). Damit sollen heutige und zukünftige Generationen vor den gesundheitlichen, sozialen und die Umwelt betreffenden Folgen des Tabakkonsums und des Passivrauchens geschützt werden. Bei der Umsetzung der im WHO FCTC geforderten Tabakkontrollmaßnahmen belegt Deutschland unter den europäischen Ländern den fünftletzten Platz (Joossens et al., 2022).

2.5 Rauchfrei-Hotline der BZgA

Eine der im WHO FCTC geforderten Maßnahmen ist die Implementierung von Quitlines (World Health Organization, 2003). Alle Vertragsparteien sollen telefonische Beratungsdienste anbieten, bei denen sich rauchende Anrufende von geschulten Spezialisten über ihren Tabakkonsum beraten lassen können. Barrieren für die Inanspruchnahme sind gering, da sie für die Anrufenden kostenlos und ohne Krankenversicherung, sowie örtlich und zeitlich flexibel zugänglich sind (Ahluwalia et al., 2021; Fiore, 2000; Fiore & Baker, 2021; Ossip-Klein et al., 1991; Zhu et al., 2002). Auch unterversorgte Gruppen wie ethnische und/oder sprachliche Minoritäten können erreicht werden (Stead et al., 2013; Zhu, 2000). Eine große Stärke liegt zudem im Potenzial von Quitlines, eine hohe Anzahl an Rauchenden erreichen zu können, bei gleichzeitiger Kosteneffektivität (Fiore, 2000; Fiore & Baker, 2021; Hollis et al., 2007; Zhu et al., 2002). Die telefonische Beratung selbst kann dabei an die individuellen Bedürfnisse einzelner Rauchender angepasst werden (Zhu et al., 1996).

Trotz der schlechten insgesamten Umsetzung des WHO FCTC konnte die geforderte Maßnahme einer nationalen Quitline in Deutschland erfüllt werden (Joossens et al., 2022). Die kostenlose Rauchfrei-Hotline wurde im Jahr 1999 implementiert und wird von der BZgA betreut. Bei einem Anruf unterstützen ausgebildete Fachkräfte hilfesuchende

Rauchende bei der Vorbereitung und Umsetzung eines Rauchstopps. Ebenso wird Unterstützung bei Rückfällen geleistet und Informationen zu Fragen rund um die Themen Rauchen und Nichtrauchen erteilt. Nach einem reaktiven Erstgespräch (Anruf durch Rauchende) können bis zu fünf proaktive Folgeanrufe (Anrufe durch Beratungspersonen) durchgeführt werden. Mehr als 21.000 Personen nahmen im Jahr 2023 dieses Angebot in Anspruch. In einer früheren Evaluation zur Wirksamkeit der Rauchfrei-Hotline wurden die Abstinenzraten von Rauchenden, die eine einmalige Beratung (reaktive Beratung) erhalten hatten, mit denen von Rauchenden, die bis zu fünf Folgeberatungen realisierten (proaktive Beratung), verglichen (Lindinger et al., 2012). Die Ergebnisse zeigen, dass Rauchende, die zusätzlich proaktive Beratung erhalten hatten, nach drei Monaten eine deutlich höhere Abstinenzrate aufwiesen als Rauchende, die einmalig beraten wurden (22,3 % vs. 11,1 %). Proaktive Beratung mit mindestens drei Folgeberatungen war auch nach einem Jahr wirksamer als eine einmalige oder weniger intensive proaktive Beratung (Punktprävalenz: 34,4 % vs. 21,3 %). Die Aussagekraft und Interpretation der Ergebnisse sind jedoch methodisch limitiert, da die Anrufenden den beiden Studiengruppen nicht zufällig zugeteilt wurden.

2.6 Untersuchte Forschungsfragen

Das Hauptziel dieser Dissertation ist es, mittels einer zwei-armigen, randomisiert, kontrollierten Studie, die Wirksamkeit der proaktiven Rauchfrei-Hotline der BZgA zu evaluieren. Dazu werden die Abstinenzraten von Teilnehmenden, die eine proaktive Telefonberatung erhalten (Interventionsgruppe), mit den Abstinenzraten von Teilnehmenden, die Selbsthilfematerialen als Minimalintervention erhalten (Kontrollgruppe), verglichen. Um der steigenden Nutzung immer neuer Konsumformen von Nikotin und Tabak zu begegnen (O'Connor, 2012), werden zwei Definitionen verwendet: Zigarettenabstinenz und Tabakabstinenz. Wie vom Netzwerk der Society for

Research on Nicotine and Tobacco (SRNT) empfohlen (Piper et al., 2020), wird zum einen die Abstinenz von konventionellen Zigaretten als Endpunkt herangezogen, um Vergleiche mit früheren Studien zu ermöglichen. Zum anderen wird, als konservativerer Endpunkt, die Abstinenz von allen verbrennbaren und rauchlosen Tabakprodukten, d. h. Zigaretten inkl. z. B. Zigarren, Pfeifen, Snus oder Heat-not-burn (HNB) Produkten, untersucht. Auf Basis früherer Studien (Matkin et al., 2019) werden höhere Abstinenzraten bei Teilnehmenden der Telefonberatung als bei Teilnehmenden, die Selbsthilfematerialien erhalten, erwartet.

Als weiteres Ziel soll diese Dissertation untersuchen, welche psychologischen Kompetenzen zur Erlangung und Aufrechterhaltung der Abstinenz (z. B. dysfunktionale rauchbezogene Kognitionen, Anwendung von Bewältigungsstrategien) durch die Telefonberatung verändert werden, d. h. welche Behandlungselemente wirksam sind. Da die Teilnehmenden in der Kontrollgruppe eine aktive Kontrollintervention erhalten werden, wird in beiden Gruppen eine Veränderung bei den psychologischen Kompetenzen zur Erlangung und Aufrechterhaltung der Abstinenz erwartet, jedoch mit einer größeren Ausprägung in der Interventionsgruppe.

Einer weiteren Empfehlung des SRNT-Netzwerks folgend (Piper et al., 2020), wird außerdem erfasst, welche zusätzlichen Hilfsmittel (NRT, E-Zigaretten, etc.) zur Unterstützung des Rauchstopps neben der Intervention genutzt werden, da die Nutzung einen Einfluss auf die Effektgrößen der Abstinenz haben könnte und bei der Interpretation der Ergebnisse ggf. berücksichtigt werden müsste. Außerdem können Informationen über die Nutzung zusätzlicher Hilfsmittel zur Optimierung des Beratungsprotokolls der Hotline herangezogen werden.

Auf Grundlage der Evaluation und Prüfung der Wirksamkeit der Rauchfrei-Hotline der BZgA lässt sich der Prozess der Telefonberatung für die Rauchentwöhnung optimieren und anpassen, um so den Bedarf einer größtmöglichen Personenanzahl zu decken.

Die untersuchten Forschungsfragen lauten dabei im Einzelnen:

- Welche kurz- und langfristigen Effekte hat die Telefonberatung im Vergleich zur Nutzung einer Selbsthilfebroschüre bei Rauchenden auf die Abstinenz (Zigaretten und Tabak)?
- Führt die Nutzung der Telefonberatung zu Veränderungen in psychologischen Kompetenzen zur Erlangung und Aufrechterhaltung der Abstinenz (Behandlungskomponenten)?
- Wie nehmen Teilnehmende die Wirksamkeit einzelner Behandlungskomponenten wahr und wie zufrieden sind sie mit der Telefonberatung?
- Wie viele Teilnehmende nutzen beim Rauchstopp-Versuch zusätzliche Hilfsmittel und welche?

Weitere Details über das Studiendesign und die Methoden finden sich im publizierten Studienprotokoll, welches in Kapitel 5 zu finden ist. Die Ergebnisse der Forschungsfragen wurden in zwei internationalen Fachzeitschriften publiziert und finden sich in abgedruckter Form in den Kapiteln 6 und 7 dieser Arbeit.

3. Zusammenfassung

Hintergrund: Tabakkonsum stellt weltweit eine erhebliche Bedrohung für die öffentliche Gesundheit dar und verursacht jährlich zahlreiche vermeidbare Todesfälle und Beeinträchtigungen. Um den negativen Auswirkungen des Rauchens auf die Gesundheit zu begegnen, sind Präventionsmaßnahmen allein unzureichend. Eine Vielzahl evidenzbasierter Rauchentwöhnungsbehandlungen muss für Rauchende verfügbar gemacht werden. Eine wirksame Maßnahme zur Reduzierung des Tabakkonsums ist die Implementierung von Rauchstopptelefonen, sogenannten Quitlines. In Deutschland wurde hierfür die Rauchfrei-Hotline der BZgA eingerichtet.

Ziele: Das Ziel dieser Dissertation ist es, die Wirksamkeit der Rauchfrei-Hotline der BZgA zu evaluieren und die Ergebnisse in zwei Publikationen darzulegen. Die Forschungsfragen beinhalten die kurz- und langfristige Wirksamkeit der Telefonberatung auf die Abstinenz, die Veränderung in spezifischen Behandlungskomponenten sowie die Nutzung weiterer Hilfsmittel zur Rauchentwöhnung (z. B. NRT, E-Zigaretten) zusätzlich zur Intervention. Die Ergebnisse liefern Informationen zur Entwicklung oder Modifikation von Beratungsprotokollen, welche z. B. auf Grund neuartiger Konsumformen notwendig werden.

Methode: Durchgeführt wurde eine zwei-armig randomisierte, kontrollierte Studie mit Datenerhebungen zu Baseline sowie drei Monate (Post-Befragung) und zwölf Monate (Follow-Up-Befragung) nach Beginn der Intervention. Täglich Rauchende, die einen Rauchstopp durchführen wollten, erhielten entweder bis zu sechs telefonische Beratungsgespräche (Interventionsgruppe) oder eine Selbsthilfebroschüre (Kontrollgruppe). Primäre Endpunkte umfassten die Sieben-Tage-Punkt-Prävalenz-Abstinenz zu drei und zwölf Monaten sowie die anhaltende Abstinenz (von der Post- zur Follow-Up-Befragung). Gemäß den Empfehlungen des SRNT-Netzwerks wurden zwei

Definitionen der Abstinenz (Zigaretten und Tabak) verwendet. Sekundäre Endpunkte umfassten Veränderungen in Behandlungskomponenten (z. B. rauchbezogene Kognitionen und Bewältigungsstrategien) von der Post- zur Follow-Up-Erhebung), die subjektiv wahrgenommene Wirksamkeit der Behandlungskomponenten und die Zufriedenheit mit der Intervention. Darüber hinaus wurde die Nutzung zusätzlicher Hilfsmittel erfasst, um Abstinenzraten umfassender interpretieren zu können.

Ergebnisse: Insgesamt wurden $n = 905$ Teilnehmende randomisiert (Intention-to-treat-Analyse). Die Interventionsgruppe ($n = 477$) zeigte statistisch signifikant höhere kurzfristige Tabakabstinenzraten (41,1 % vs. 23,1 %; $OR = 2,3$; 95 %-KI [1,7, 3,1]) und erreichte mit höherer Wahrscheinlichkeit langfristige Zigarettenabstinenz (31,7 % vs. 17,8 %) und langfristige Tabakabstinenz (30,8 % vs. 15,2 %) im Vergleich zur Kontrollgruppe ($n = 428$), mit entsprechenden Odds-Ratios (*OR*) von 2,2 (95 %-KI [1,6, 3,0]) und 2,5 (95 %-KI [1,8, 3,5]). Teilnehmende beider Studiengruppen, die die Intervention erhielten ($n = 653$; Complete-Case-Analyse), zeigten statistisch signifikante Zuwächse in rauchbezogenen Kognitionen und Bewältigungsstrategien, wobei die Interventionsgruppe höhere Zuwächse als die Kontrollgruppe aufwies. Dieses Muster wurde auch hinsichtlich der wahrgenommenen Wirksamkeit der Interventionskomponenten und der Zufriedenheit mit der Intervention beobachtet. E-Zigaretten waren das am häufigsten genutzte zusätzliche Hilfsmittel zur Rauchentwöhnung (46,0 %), gefolgt von elektronischen Medien (31,0 %) und NRT (26,2 %).

Schlussfolgerungen: Die Ergebnisse liefern erstmalig empirische Evidenz für die Wirksamkeit der proaktiven Telefonberatung durch die deutsche Rauchfrei-Hotline der BZgA hinsichtlich der Förderung der Abstinenz von Zigaretten und Tabak. Dies unterstreicht ihr Potenzial als wirksame öffentliche Gesundheitsintervention zur

Reduzierung der mit dem Rauchen verbundenen Krankheitslast. Eine erhöhte Bekanntmachung und Nutzung der Hotline könnten ihre Auswirkungen auf die Rauchstopp-Raten in Deutschland verbessern. Darüber hinaus sollte das Beratungsprotokoll auf Grund der zunehmenden Popularität neuartiger Konsumprodukte von Nikotin und Tabak Informationen zu deren Risiken und Potenzial als Rauchentwöhnungshilfen integrieren.

4. Abstract

Background: Tobacco consumption poses a significant threat to public health worldwide, leading to numerous preventable deaths and disabilities annually. To reverse the negative impact of smoking on health, prevention efforts are not enough. A variety of evidence-based cessation treatments need to be made available to smokers. An effective measure for reducing tobacco consumption is the implementation of telephone counselling services. In Germany, the national Quitline for smoking cessation by the Federal Centre for Health Education (BZgA) has been established for this purpose.

Objectives: This dissertation aims to evaluate the effectiveness of the national German quitline for smoking cessation and to publish two studies demonstrating the results. Key research questions include the short- and long-term effectiveness of telephone counselling on smoking abstinence, the effectiveness of specific treatment components, and the use of additional cessation aids (e.g., nicotine replacement therapy, e-cigarettes) alongside the intervention. The results provide information on the development or modification of quitline counselling protocols, e.g., due to novel consumer products.

Methods: A parallel-group, two-arm, superiority, randomized controlled trial with data collected at baseline as well as 3 (post assessment) and 12 months (follow-up assessment) after the start of the intervention was conducted. Daily smokers, willing to quit, received either up to six telephone counselling calls (intervention group) or a self-help brochure (control group). Primary outcome measures included the 7-day point prevalence abstinence at 3-month and 12-month assessments as well as prolonged abstinence (abstinence over the 12 month period). As recommended by the SRNT Treatment Research Network, two definitions of abstinence (cigarette and tobacco) were applied. Secondary outcomes included changes in smoking-related cognitions and coping strategies from pre- to post-assessment, the perceived effectiveness of intervention

components, and the satisfaction with the intervention. Further, the use of additional cessation aids was assessed, to contribute to a better interpretation of the findings on abstinence.

Results: A total of $n = 905$ participants were randomized (intention-to-treat). The intervention group (n = 477) exhibited statistically significantly higher short-term tobacco abstinence (41.1% vs. 23.1%; *OR* = 2.3, 95% CI [1.7, 3.1]) and was also more likely to achieve long-term cigarette abstinence (31.7% vs. 17.8%) and long-term tobacco abstinence (30.8% vs. 15.2%) compared to the control group ($n = 428$) with corresponding odds ratios (*OR*) of 2.2 (95% CI [1.6, 3.0]) and 2.5 (95% CI [1.8, 3.5]). Participants in both study groups who received the intervention ($n = 653$; complete case) displayed significant improvements in smoking-related cognitions and coping strategies, with the intervention group showing greater enhancements than the control group. This pattern was also found regarding the perceived effectiveness of intervention components and satisfaction with the intervention. E-cigarettes were the most commonly used additional cessation aid (46.0%), followed by electronic media (31.0%) and nicotine replacement therapy (26.2%).

Conclusions: The results provide the first empirical evidence on the effectiveness of proactive telephone counselling by the national German quitline for smoking cessation in promoting abstinence from cigarettes and tobacco. This highlights its potential as an effective public health intervention to reduce the burden of disease associated with smoking. Increased awareness and use of the quitline could enhance its impact on cessation rates in Germany. Additionally, given the rising popularity of novel nicotine consumer products, counselling protocols should incorporate information on their risks and potential as cessation tools.

5. Publikation I

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Effectiveness of the national German quitline for smoking cessation: study protocol of a randomized controlled trial

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Abstract

Background: Despite the decline in cigarette smoking prevalence during nearly the past two decades, tobacco use is still widespread in the German adult population, accounting for 125,000 deaths each year and causing tremendous social costs. To accelerate the reduction in tobacco smoking prevalence, evidence-based smoking cessation methods are pivotal to a national tobacco control strategy. The present study aims to evaluate the effectiveness of the national German Smokers Quitline offering cessation support to smokers.

Methods: A total sample of 910 daily smokers, who are motivated to quit, will be recruited via an online access panel and randomly assigned to either the intervention (telephone counselling) or control condition. In the intervention group, participants will receive up to six proactive phone calls during an intervention period of approximately six weeks. The provided treatment will combine the principles of motivational interviewing and those of the cognitive behavioural approach to treating substance use. Participants in the control condition will receive a self-help brochure to support smoking cessation. Data collection will take place at baseline as well as three (post assessment) and twelve months (follow-up assessment) after baseline assessment. Primary outcome measures will include the seven-day point prevalence abstinence at 3-month and 12-month assessments as well as prolonged abstinence (abstinence over the 12 month period). Secondary outcome measures will include a change in smoking-related cognitions and coping strategies among all participants. Among non-abstainers, treatment success indicators such as a reduction in number of cigarettes smoked per day and changes in the number and duration of quit attempts after intervention start will be assessed. It is expected that after both three and twelve months, smoking cessation rates will be higher in the telephone counselling condition compared to the control condition.

Discussion: The results will provide insights into the effectiveness of proactive telephone counselling by the national German Smokers Quitline.

Trial registration: The protocol for this study is registered with the German Clinical Trials Register: DRKS00025343, Date of registration: 2021/06/07, https://www.drks.de/drks_web/setLocale_EN.do

Keywords: Smoking cessation, Telephone counselling, Randomized controlled trial, Quitline, Helpline, Tobacco smoking

Background

Despite the decline in cigarette smoking prevalence over the past two decades, cigarette smoking remains the leading cause of preventable disease, disability, and death globally accounting for 8.71 million deaths in 2019

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[1]. With 14.4 million current smokers in 2018, tobacco use is still widespread in the German adult population [2]. To further accelerate the reduction in tobacco smoking prevalence, federally available and effective smoking cessation interventions are needed and central to a successful tobacco control policy [3]. International efforts for tobacco interventions have been strengthened by the World Health Organization's Framework Convention on Tobacco Control (WHO FCTC) [4]. The WHO FCTC has been developed to protect current and future generations from the health, social, and environmental consequences of tobacco use and second-hand smoke [4]. One effective measure proposed by the FCTC is the availability of telephone counselling services to support smoking cessation by trained specialists [5].

Telephone counselling services for smoking cessation are recommended because they have the potential to reach a large number of smokers [6, 7], particularly due to their flexibility in terms of time and location. They can also provide treatment to underserved groups, such as ethnic and/or linguistic minorities [8, 9], to smokers who are geographically dispersed and are attractive to smokers seeking low threshold support [10–13]. Moreover, they have the ability to tailor the intervention to key recipient characteristics and therefore offer individualized tobacco cessation to smokers [14]. Although abstinence rates achieved through telephone counselling are lower than those attained by face-to-face counselling, quitlines are effective [15] and highly cost-effective [16] due to their extraordinary reach of the smoking population [17]. For these reasons, quitlines can be considered a measure with major public health potential [18]. The effectiveness of telephone counselling for smoking cessation has been demonstrated in a systematic review [15], which shows that smokers who had called quitlines and received proactive telephone counselling were 1.38 times more likely to become abstinent than smokers who were supported by self-help materials or brief counselling at a single call (minimal intervention controls). This means that they increased their chances of long-term cessation (at least 6 months after start of the intervention) from 7 to 10%. Moreover, three to five proactive calls seem to be more effective than fewer calls [15].

Germany implemented its national Smokers Quitline in 1999. It is overseen by the Federal Centre for Health Education ['Bundeszentrale für gesundheitliche Aufklärung, BZgA'] and offers reactive telephone counselling (calls initiated by the smoker) with a maximum of five proactive follow-up calls (calls initiated by the counsellor). Trained specialists advise smokers seeking support in smoking cessation, former smokers experiencing a relapse crisis, and information seekers who intend to quit. In 2021, more than 33,000 German smokers contacted the national Smokers Quitline. In a previous evaluation, it was found that smokers who received proactive counselling (several counselling sessions) from the national German Smokers Quitline had significantly higher abstinence rates three months after the intervention than smokers who received reactive counselling (one-time counselling) (22.3% vs. 11.1%) [19]. In this study, participants were not randomly assigned to one of the two study conditions.

As the impact of the national German Smokers Quitline could be increased by optimizing the offered intervention, the overall goal of the current study is to conduct a two-arm randomized controlled trial to evaluate the effectiveness of the national German Smokers Quitline. To accomplish this, abstinence rates will be compared among smokers, who will receive proactive telephone counselling and smokers who will receive a self-help brochure. Based on previous research [15], we expect higher smoking cessation rates among participants in the telephone counselling condition compared to the control condition (primary outcome). In addition, we hypothesize that telephone counselling will increase quit attempts, the occurrence of 24-hour abstinence, the motivation to quit, the implementation of smoking restrictions at home, and reduce daily cigarette consumption and nicotine dependence levels among non-abstainers three and twelve months after start of the intervention (secondary outcomes).

Methods

Study design

The present evaluation is designed as a parallel-group, superiority, two-arm randomized controlled trial with 1:1 allocation ratio. The evaluation comprises three assessments within a period of approximately one year. Data collection will take place at baseline, three months (post assessment) and twelve months (follow-up assessment) after baseline assessment. The study design and participant flow are outlined in the Consolidated Standards for Reporting Trials (CONSORT) diagram (Fig. 1). After giving informed consent and completion of the baseline survey, participants will be randomly assigned to the intervention or control group. In the intervention group, participants will receive telephone counselling from counsellors of the national German Smokers Quitline, while in the control group they will be provided with a self-help brochure to support smoking cessation. Self-help materials were chosen as treatment in the control condition, as participants may have a benefit compared to receiving no intervention [20]. Moreover, it is considered unethical to recruit participants for a smoking cessation treatment when subsequently not offering an intervention. Providing an alternative intervention for the control

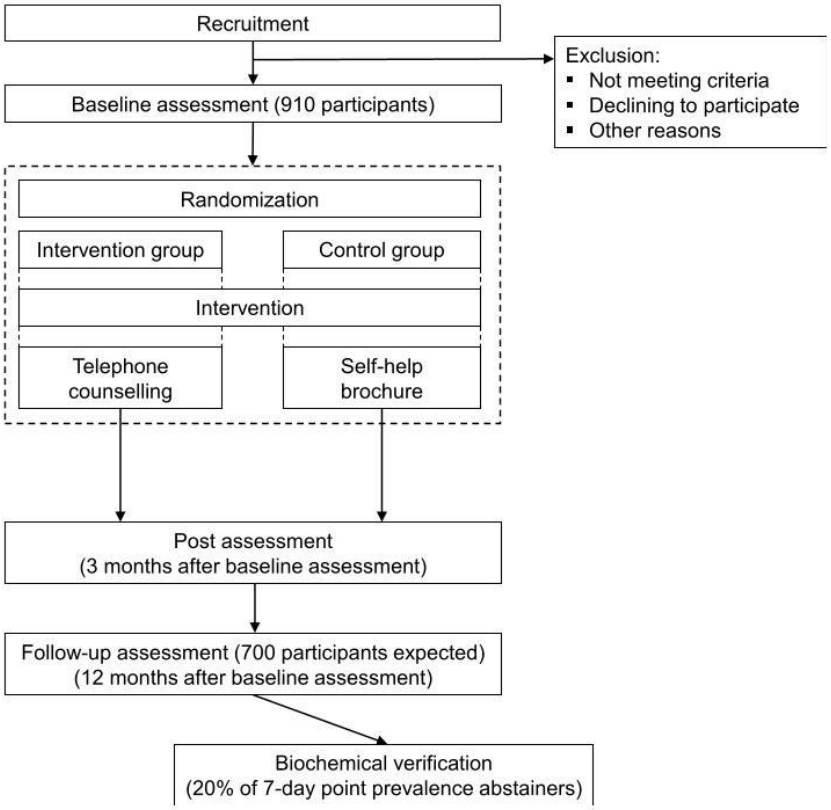

Fig. 1 Consolidated Standards for Reporting Trials (CONSORT) diagram: study design and participant flow

group may also help achieve comparable response rates. To allow correction for any overreporting of abstinence, abstinence will be biochemically verified for a random sample of study participants who report abstinence at 12-month follow-up.

Sample size calculation

To calculate the required sample size, a power analysis was carried out using the software G*Power [21]. Based on previous studies examining the effects of telephone smoking counselling and the use of self-help materials on seven-day-point-prevalence abstinence rates [15], a small effect size was expected. Assuming a significance level of 5% and statistical power of 0.8, the estimated required sample is $N=700$ participants (350 participants per study condition). The calculated sample size was corrected by a 30% dropout rate [7], resulting in a total sample size of $N=910$ enrolled participants.

Procedure

Smokers residing in Germany will be recruited by a market research company using the PAYBACK panel, which exists since 2007. PAYBACK panelists are recruited through PAYBACK, which is the largest customer loyalty program, covering half of the German households. The panel is composed of more than 130.000 adults and is one of the largest online access panels in Germany. Panel members will be screened for eligibility by email (that contains a link to the digital questionnaire). Eligible participants will be required [1] to be at least 18 years old, [2] to have smoked cigarettes on a daily basis in the past 30 days, [3] to intend to quit smoking in the following month and [4] to provide informed consent prior to participation. Contact details of participants will be transferred to the study site twice a week. To improve adherence to the intervention protocols, referred smokers will be contacted by telephone prior to baseline assessment. During this call, they will again be informed about the procedure of the study and possible questions will be answered. Consented participants will complete the digital baseline questionnaire which will validate eligibility criteria before randomization. At least two weeks after completing the screening questionnaire, participants will either receive the self-help brochure or a call

from a quitline counsellor. Three and 12 months after baseline assessment, participants will obtain another email with links to the respective questionnaires.

Participants are obliged to give study consent prior to accessing the online questionnaires. For convenience, all participants will be offered the option to complete the questionnaires via telephone interviews. Participants will receive a €25 voucher for the baseline assessment and a €15 voucher for the post and follow-up assessment respectively. For taking part in the biochemical verification, an additional remuneration of €30 will be offered. Moreover, several shopping vouchers will be raffled among participants who complete the entire study.

Randomization

Randomization will be conducted by a research staff member. To ensure equal distribution of participants concerning selected key characteristics, randomization will be stratified based on four strata: number of cigarettes smoked per day (1–10/11–20/21–30/> 30 cigs per day), sex (female/male/diverse), age (18–30/ 31–64/> 64 years old) and level of education (low/middle/high) as reported by participants at baseline. The numbers of participants receiving each intervention are closely balanced within each stratum by performing a separate randomization procedure using permuted blocks (with each recruitment session as a block) of varying length. The first study participant per block (ordered randomly using the RAND function, Microsoft Excel) is randomized into the intervention group, the second one into the control group and so on. The randomization procedure is documented and maintained using a list which contains all possible combinations of strata and their levels as well as the number of participants in each group per strata combination. If the groups differ due to an imbalance in a certain strata combination (difference > 5 participants), the next participant with the respective strata combination will be allocated to the underrepresented group until an equal distribution is achieved.

Allocation concealment will be ensured, as participants will not be assigned to one of the study conditions until baseline measurements have been completed. Due to the nature of the intervention, neither participants nor staff can be blinded to allocation. In the study material, participants will be informed about the two study conditions. However, participants will be blinded to the study hypothesis in terms of which intervention is considered active.

Interventions

Telephone counselling condition

The national German Smokers Quitline offers telephone counselling to smokers seeking support in smoking cessation, to former smokers experiencing a relapse crisis, and to information seekers. The majority of counsellors are non-academic health professionals such as nurses. Counsellors receive an intensive three-day training following the WHO training protocol "Quitline Counselling" which includes amongst other things the training on the used counselling software, the simulation of calls as well as on-site observation of experienced counsellors.

The counselling follows a structured, yet flexible counselling protocol based on the protocol of the California Smokers' Helpline [14]. The principles of this protocol are built upon the theory of social learning [22, 23], which emphasizes the client's capacity for self-regulation and the relevance of self-efficacy in behaviour change [14]. Therefore, the protocol combines the principles of motivational interviewing (MI) (Miller & Rollnick, 1991) and those of the cognitive behavioural approach to treating substance use e.g. [14, 24]. MI is used to induce behaviour change by enhancing the client's intrinsic motivation to change. An empathetic, non-confrontational conversation style generates a collaborative counsellor-client relationship and allows to address the clients` ambivalence [25]. Once a client is ready to quit smoking, the counsellor applies cognitive-behavioural strategies. The client is encouraged to identify and restructure dysfunctional cognitions about smoking and quitting and to develop and implement coping strategies [14, 26]. A central tenet of this complementary approach is the counsellor's continuous monitoring and fostering of the client's motivation to quit and the support to increase self-management skills and self-efficacy to change [14]. Adherence to the counselling protocol is assessed on a regular basis by analyzing recorded calls and digital counselling notes taken by the counsellors.

In the telephone condition, based on their needs, participants can receive up to six proactive phone calls (14, for detailed information see 19). The first session (intake session) will take 20 to 25 minutes and will focus on assessing the client's smoking and quitting history, their smoking habits and their motivation to quit. Moreover, the counsellor aims to resolve ambivalent feelings, to strengthen the client's self-efficacy and motivation to quit, to identify difficult situations and to develop strategies for coping with the urge to smoke. Finally, the counsellor will encourage the client to set a quit date within the next 14 days. Participants are then offered up to five follow-up calls to support relapse prevention and the maintenance of smoking cessation. The first follow-up session will take place approximately two to three days after the quit date, the second will take place approximately seven days after the quit date; the third approximately twelve days, the fourth approximately three weeks

and the fifth follow-up call approximately one month after the quit date. These sessions take about ten minutes each and cover the following topics: Assessing the client's progress and evaluating the effectiveness of applied coping strategies, discussing withdrawal symptoms, the urge to smoke and self-efficacy as well as examining difficult situations and their handling.

Self-help condition

In the control condition, participants will receive the self-help brochure 'Ja, ich werde rauchfrei!' ['Yes, I'll be smoke-free'] which is being disseminated by the Federal Centre for Health Education [27]. The 92-page booklet is directed at individuals attempting to achieve smoking cessation. It follows the principles of cognitive-behavioural therapy [26] and guides the reader step by step from preparing to quit to long-term abstinence. The brochure is divided into the parts: information about smoking and smoking cessation, preparing and planning for smoking cessation and information on topics related to maintaining abstinence (e.g., anticipation of potential high-risk situations, smoking urges, developing the identity of a non-smoker, use of cognitive and behavioral coping responses, keeping weight gain in perspective, finding other forms of positive reinforcement, management of stress). Participants in the control condition will be offered telephone counselling at the end of the study.

Outcomes

Outcome measures and covariates with their respective assessment time points are shown in Table 1.

Primary outcomes

In accordance with the Russell standard criteria [28], primary outcome measures will include (1) seven-day point prevalence abstinence at 3-month post and 12-month follow-up assessment, (2) prolonged abstinence (abstinence over the 12 month period allowing up to five cigarettes in total), and (3) biochemical verification of abstinence in 20% of the abstainers at 12-month follow-up. To define abstinence, cut-off scores of 8 ppm for CO will be used [29].

Secondary outcomes

Among participants who report being non-abstinent at 3- and 12-month follow-up, secondary outcome measures will include: (1) changes in number of cigarettes smoked per day and in nicotine dependence levels [30], (2) the number and duration of quit attempts after intervention start [31, 32], (3) the occurrence of abstinence of at least 24 hours at some point during the study (4), [31] an increase in motivation to quit (5), [33] the implementation of smoking restrictions at home [34]. A change in smoking-related cognitions (smoking outcome expectancies [35, 36]; self-efficacy to refrain from smoking [36–38]; self-efficacy for abstinence [39]) and coping strategies (avoidance of external cues [40]; perceived control over withdrawal symptoms [41]) will be assessed among all participants.

Covariates

The following covariates will be assessed: (1) sociodemographic characteristics (gender, age, education, employment status, nationality, marital status), (2) smoking-related variables (use of other tobacco products, years smoking, number and frequency of previous quit attempts [42], confidence in quitting and importance to quit, craving [43], other smoking household members, smoking behaviour of the partner, use of and adherence to additional supportive materials (e.g., NRT, pharmacotherapy, e-cigarettes, heat-not-burn products)), (3) health status (depressive symptoms [44], selected smoking-related illnesses, mental comorbidity), (4) received social support (supportive network and overall quitting support [45]), and (5) the use and acceptability of the received intervention (telephone counselling or self-help brochure) [31].

Data collection and management

Participants will be recruited consecutively between October 2021 and June 2022. Therefore, data collection will take place at different time points (at baseline, three months and twelve months after baseline assessment) over a period of approximately two years. Data will be collected via online questionnaires using the software SoSci Survey [46]. It is expected that the majority of questionnaires will be administered digitally (compared to phone interviews). In order to biochemically verify abstinence, 20% of study participants who will report abstinence at 12-month follow-up and who consented to participate will be randomly selected. Research staff will meet participants at their preferred location and will collect breath carbon monoxide (CO) using a portable CO monitor.

Once a participant is enrolled, the study site will make every reasonable effort to follow the participant for the entire study period. Various procedures will be used to reduce attrition, including reminder emails and calls, flexible scheduling of the counselling sessions, and incentives for completing the questionnaires. It is expected that the rate of loss-to-follow-up will not exceed the calculated 30%. To enhance validity of data, multiple methods will be used to assess intervention adherence including the phone call prior to enrolment in order to answer possible questions and questionnaire items on

Table 1 Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) diagram

	STUDY PERIOD						
	Recruitment	Enrolment	Allocation	Post-allocation			
TIMEPOINT	$-t_2$	$-t_1$	0	t_1	t_2	t_3	t_4
	Screening	Baseline assessment	Randomization	Intervention	Post assessment	Follow-up assessment	Biochemical verification
ENROLMENT:							
Eligibility screen	X						
Informed consent	X	X			X	X	X
Randomization			X				
INTERVENTIONS:							
Telephone counselling				X			
Self-help brochure				X			
ASSESSMENTS:							
Socio-demographic characteristics	X	X					
Smoking-related variables		X			X	X	
Health status		X			X		
Received social support					X		
7-day point prevalence abstinence					X	X	
Prolonged abstinence						X	
Number of cigarettes smoked per day	X	X			X	X	
Nicotine dependence		X			X	X	
Number and duration of quit attempts					X	X	
Occurrence of abstinence of at least 24 hours					X	X	
Motivation to quit	X	X			X	X	
Implementation of smoking restrictions at home		X			X	X	
Smoking-related cognitions		X			X		
Coping strategies		X			X		
Use and acceptability of the received intervention					X		
Breath carbon monoxide (CO)							X

Note: -t2: recruitment of participants by a market research company using a screening questionnaire; −t1: baseline assessment; 0: randomization of participants to either the intervention or control condition; t1: intervention (telephone counselling or self-help broschure); t2: post assessment 3 months after baseline assessment; t3: follow-up assessment 12 months after baseline assessment; t4: biochemical verification: 20% random sample of participants who reported 7-day point prevalence abstinence at 12-month assessment

the use and acceptability of the received intervention at 3-month post assessment.

All participant data is handled in accordance with the General Data Protection Regulation (GDPR). All data will be maintained confidentially before, during, and after the trial and is stored securely at the study site with access only by dedicated study team members. All substantial procedures are described in the application for the Ethics Committee and can be provided on request. The final data set will be stored for 10 years after completion of the study. A data monitoring committee is not considered necessary as participants are not blinded to the study conditions and as this is a short-term, non-invasive intervention with the opportunity to quit at any time without any negative consequences or side-effects.

Statistical analyses

Descriptive analyses will be conducted to examine whether randomization has resulted in an equal baseline distribution of participants regarding relevant

characteristics across the two conditions using χ^2-tests and *t*-tests. To account for any possible group differences at baseline, confounding variables will be included in subsequent analyses. We will use logistic regression models and analyses of variance to evaluate the effectiveness of the intervention by comparing smoking cessation rates across groups. Effect sizes, as well as confidence intervals, will be reported. To analyze abstinence rates, the intention-to-treat (ITT) approach will be used. This means that data of all randomized participants will be included in the analyses unless they are deceased or have moved to an untraceable address, as recommended by the Russell Standard criteria (RS) [28]. Participants with undetermined smoking status at follow-up will be counted as smokers. In addition to the ITT principles, a complete-case analysis will be performed, in which only participants with outcome data on all assessments will be included. As all assessments use a forced entry format, no imputation for missing values will be needed. All analysis will be conducted using the statistical program R and R Studio [47, 48].

Discussion

This study protocol presents the design of a two-arm randomized controlled trial with baseline, post and follow-up assessments to examine the effectiveness of proactive telephone counselling for smoking cessation by the national German Smokers Quitline. A major aim of the national German Smokers Quitline is to provide free counselling to smokers who want to quit smoking and thereby decrease smoking rates in the German population.

In the intervention condition, smokers will receive counselling from the national German Smokers Quitline, while in the control condition, they will receive a self-help brochure to support smoking cessation. Both interventions are based on the principles of cognitive-behavioural therapy [26], however, smokers in the intervention condition can receive structured but tailored counselling in multiple sessions up to six weeks length. Based on previous research [15, 31], it is expected that smoking cessation rates will be higher in the intervention than in the control condition three as well as twelve months after the intervention. In addition, we hypothesize that telephone counselling will increase quit attempts, the occurrence of 24-hour abstinence, the motivation to quit, the implementation of smoking restrictions at home, and reduce daily cigarette consumption and nicotine dependence levels among non-abstainers.

The current study is the first to examine the effectiveness of the national German Smokers Quitline using a randomized design with post and follow-up assessments allowing to test the short- and long-term effects of the intervention. The assessment of abstinence at twelve-month follow-up is recommended as it is more closely related to life-long abstinence and false-positive results are less likely [49]. Another strength of the current study lies in the application of RS criteria for trials of cessation aids [28, 50], which enhances the quality of the data and the generalizability of the results. One limitation of this study is the assessment of abstincence via self-reports, although self-reports have previously been shown to be reliable and valid measures of respondents' smoking behaviour [51]. Additionally, in a subsample of all study participants who report 7-day point prevalence at follow-up, smoking cessation will be biochemically verified to counteract reporting biases [29, 31]. Another limitation of this study is that participants will be recruited via an online panel, which may limit the generalizability of study results.

Quitlines are considered an important and cost-effective population-based tobacco control strategy [17]. However, of the 19.9% of German current and recent former smokers who try to quit smoking per year, only 13.0% use at least one evidence-based method to support their cessation attempt. The majority of smokers does not make use of quitlines; they reach only about 0.8% of individuals who make a quit attempt [52]. If the intervention provided by the national German Smokers Quitline is found to be effective, awareness should be enhanced to exploit the proportion of smokers that are advised to stop smoking through telephone counselling. Its population-based impact, which means an increased use of the quitline services, could be expanded by communication campaigns. The recruitment for quitline services can be further enhanced by targeting populations that have a high tobacco use prevalence [17]. The results of the current study will provide insights into the effectiveness of the national German Smokers Quitline.

Abbreviations

BZgA: Bundeszentrale für gesundheitliche Aufklärung, Federal Centre for Health Education; CO: Carbon monoxide; CONSORT: Consolidated Standards for Reporting Trials; DGPs: Deutsche Gesellschaft für Psychologie, German Psychological Society; DRKS: Deutsches Register klinischer Studien; FCTC : Framework Convention on Tobacco Control; GDPR: General Data Protection Regulation; IFT: Institut für Therapieforschung; MI: Motivational interviewing; NRT: Nicotine replacement therapy; RS: Russell Standard; SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials; WHO: World Health Organization.

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Authors' contributions

SD, KL and LK designed the study. SD, SM, KL and LK did the conceptional work. SD wrote a first draft of the manuscript. KL, LK, EH and OP revised the

manuscript. All authors approved the final version of the manuscript for publication.

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Availability of data and materials
Anonymized study data and statistical codes to analyses may be made available on request from the corresponding author following study closure.

Declarations

Ethics approval and consent to participate
This study has been approved by the Ethics Committee of the German Psychological Society (DGPs). It follows the Consolidated Standards of Reporting Trials (CONSORT) [53] and meets the guidelines and methodology of the Standard Protocol Items Recommendations for Interventional Trials (SPIRIT) [54, 55]. It complies with the principles stipulated in the Declaration of Helsinki [56]. The study is registered in the DRKS public database (trial registration number DRKS00025343). All substantial protocol deviations or modifications will be communicated to the Ethics Committee and the DRKS. Upon enrollment, participants will provide written informed consent. The consent form will be provided on request.

Consent for publication
Not applicable. The study results will be presented at conferences and will be submitted for publication in relevant journals.

Competing interests
The authors declare that they have no competing interests.

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RESEARCH Open Access

Short-term effectiveness of the national German quitline for smoking cessation: results of a randomized controlled trial

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Abstract

Background The objective of the present study was to examine the short-term effectiveness of the national German quitline for smoking cessation.

Methods A parallel-group, two-arm, superiority, randomized controlled trial with data collection at baseline and post-intervention (three months from baseline) was conducted. Individuals were randomized to either the intervention group, receiving up to six telephone counselling calls, or the control group, receiving an active control intervention (self-help brochure). The primary outcome was the seven-day point prevalence abstinence at post-assessment. Secondary outcomes included changes in smoking-related cognitions and coping strategies from pre- to post-assessment, the perceived effectiveness of intervention components, and the satisfaction with the intervention.

Results A total of $n = 905$ adult daily smokers were assigned to either the intervention group ($n = 477$) or the control group ($n = 428$). Intention-to-treat analyses demonstrated that individuals allocated to the telephone counselling condition were more likely to achieve seven-day point prevalence abstinence at post-assessment compared to those allocated to the self-help brochure condition (41.1% vs. 23.1%; $OR = 2.3$, 95% CI [1.7, 3.1]). Participants who received the allocated intervention in both study groups displayed significant improvements in smoking-related cognitions and coping strategies with the intervention group showing greater enhancements than the control group. This pattern was also found regarding the perceived effectiveness of intervention components and the satisfaction with the intervention.

Conclusion The present study provides first empirical evidence on the short-term effectiveness of the national German quitline for smoking cessation, highlighting its potential as an effective public health intervention to reduce the burden of disease associated with smoking.

Trial registration This study is registered in the German Clinical Trials Register (DRKS00025343). Date of registration: 2021/06/07.

Keywords Smoking cessation, Telephone counselling, Randomized controlled trial, Quitline, Helpline, Tobacco smoking

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Introduction

Quitlines or telephone tobacco cessation services have been recognized as an effective public health measure [1]. Evidence suggests that telephone counselling can be a promising solution to reach a large number of the smoking population [2, 3]. Additionally, quitlines can facilitate the dissemination of evidence-based smoking cessation treatments [4, 5] by offering treatment to smokers who do not have the resources or the opportunity to access these in other settings. Overall, tobacco consumption remains one of the leading preventable contributors to both morbidity and mortality worldwide [6]. Beyond its health impact, the economic burden of tobacco-related healthcare expenses and decreased productivity is substantial [7, 8]. National quitlines might have the potential to enhance the availability and accessibility to smoking cessation treatments while maintaining treatment efficacy as well as cost-effectiveness [9–12].

Counselling by phone represents a delivery format for smokers who prefer therapist contact while alleviating barriers of physically attending a counselling service [13]. Like individual face-to-face behavioral support, telephone counselling can be tailored to the characteristics of the recipient and maximize the level of support around the needs of an individual [10, 13]. Another advantage of quitlines is that they can provide immediate cessation support [14]. Moreover, telephone counselling may be a feasible way to provide individual counselling to underserved groups, such as ethnic minorities [12, 15] or younger people [16, 17]. A recent systematic review, including 104 trials and 111,653 participants, has shown that proactive telephone counselling (calls initiated by a counsellor) for smoking cessation leads to higher rates of achieving abstinence when compared to minimal intervention controls (risk ratio (*RR*) = 1.25, 95% confidence interval (CI) [1.15 to 1.35]) [10].

Counselling services provided by quitlines have usually applied cognitive behavioral therapy (CBT) and the practice of motivational interviewing (MI) [1, 13, 18–21]. Components typically included in CBT-based smoking cessation interventions are the identification and change of maladaptive thought and behavior patterns [22, 23], the development of problem-solving and coping skills based on relapse prevention theory [18, 20], and the enhancement of self-efficacy [20, 24]. MI is a client-centered approach, that seeks to strengthen the commitment and the motivation for behavior change through the exploration and resolution of ambivalence between a person's values and their current behaviors [19]. One study has demonstrated that CBT and MI-based quitline counselling leads to changes in psychological processes [25]. Specifically, it was found that quitline support effectively reduced positive expectations related to smoking outcomes, alleviated negative affect, enhanced self-efficacy, and increased the avoidance of external cues to smoking, while fostering the acceptance of internal cues [25].

In 2003, the World Health Organization (WHO) adopted the WHO Framework Convention of Tobacco Control (WHO FCTC) [26], providing a global response to the health and economic challenges posed by tobacco use. To assist countries in enforcing the comprehensive tobacco control policies described in the FCTC, the technical package called MPOWER was launched [27]. One of the cost-effective demand-reduction elements of the MPOWER strategy is "O – Offer help to quit tobacco use", for example by enhancing the availability of telephone counselling services [27]. According to the Tobacco Control Scale, which demonstrates the implementation of tobacco control policies at the country level in Europe, Germany ranked among the lowest five countries in 2021 [28]. The establishment of a national quitline, however, represents one of the few proposed measures that have been implemented [28]. The Federal Centre for Health Education oversees the national quitline offering reactive telephone counselling (calls initiated by the smoker) with a maximum of five proactive follow-up calls (calls initiated by the counsellor). Despite its implementation in 1999, the counselling services of the national German Smokers Quitline have not yet been examined empirically. While the implementation of tobacco control policies is necessary, it is equally important to evaluate whether those measures are effective.

In the current study, we aimed to investigate the short-term effects of counselling services of the national German Smokers Quitline on smoking cessation. To accomplish this, we compared the abstinence rates of smokers, who received pro-active telephone counselling with those of smokers who received an active control treatment (i.e., a self-help brochure) three months from baseline (primary outcome). In addition, we investigated these effects on changes in dysfunctional smoking-related cognitions, in self-efficacy, and the acquisition of coping strategies as well as on participants' perceived effectiveness of intervention components and on their satisfaction with the intervention (secondary outcomes). Based on previous research [10], we expected that participants in the telephone counselling condition would be more likely to achieve abstinence compared to individuals in the control condition. Given that smokers in the control condition received an active control intervention, we hypothesized that smokers in both conditions would show changes in smoking-related cognitions and coping strategies over time but that this effect would be greater for those in the intervention group. Additionally, greater perceived effectiveness of intervention components and

satisfaction with the treatment were expected in the intervention group compared with the control group.

Methods

Study design

The present study employed a parallel-group, superiority, two-arm randomized controlled trial (RCT) design. Participants were stratified and randomly assigned to proactive telephone counselling (intervention group) or a self-help brochure (control group). Data collection took place at baseline (t_0), as well as three (t_1) and twelve months (t_2) after baseline assessment. For the current analyses, data from t_0 and t_1 was considered.

Sample size

To calculate the required sample size, a power analysis was carried out using the software G*Power [21]. Based on previous studies examining the effects of telephone smoking counselling and the use of self-help materials on seven-day-point-prevalence abstinence rates [10], a small effect size was expected. Assuming a significance level of 5% and statistical power of 0.8, the estimated required sample is $n = 700$ participants. The calculated sample size was corrected by a 30% dropout rate at t_2 [7], resulting in a total sample size of $n = 910$ enrolled participants.

Procedure

Participants were recruited by a market research company from October 2021 to July 2022 using face-to-face interviews, social media (Instagram and Facebook), and the PAYBACK panel. PAYBACK is the country's largest customer loyalty program used by approximately half of German households. Its panel consists of over 130,000 adults, being one of Germany's largest online access panels. Information about the study, along with a link to a digital screening survey, was provided to individuals either via email or directly through advertising. Individuals who had a minimum age of 18 years, reported having smoked at least one cigarette per day within the past 30 days, intended to quit smoking within the next four weeks, and wanted to participate in a research study were deemed eligible. A link to the baseline questionnaire (t_0) and a personal identifier were sent to eligible individuals via email. The baseline assessment included an overview of the study and participants were asked to provide informed consent digitally. Once consent was obtained, participants completed the questionnaire on sociodemographics and smoking-related behavior.

Individuals who provided informed consent, completed the questionnaire and met the inclusion criteria once again were stratified and randomized in a 1:1 allocation ratio to one of the two study groups. Stratification was based on four criteria: (a) number of cigarettes smoked per day (1–10, 11–20, 21–30, > 30), (b) sex (female, male, non-binary), (c) age (18–30, 31–64, > 64), and (d) educational level (low, middle, high; [29]). Following the randomization procedure, participants were informed by email to which group they had been assigned and received the respective intervention no longer than two weeks after randomization. Individuals in the intervention group were contacted up to three times by the telephone counsellors to start the intervention and participants in the control group were called a maximum of five times by the study team to confirm receiving the self-help brochure. If necessary, the brochure was re-sent.

Three months after the baseline assessment, participants were invited by email to complete the post-questionnaire (t_1). In case of non-response, the study team sent a maximum of two reminder emails and called once to encourage completion. Participants could earn up to 40€ for completing both questionnaires. For more detailed information, see the study protocol [30].

Interventions

Proactive telephone counselling

The national German quitline for smoking cessation provides telephone counselling to smokers who want to quit smoking soon (i.e., in the next two weeks). The counselling protocol covers two phases of smoking cessation: preparing to quit (one session) and the maintenance of smoking cessation and relapse prevention after quitting (up to five sessions afterward). The counselling process is structured but can be tailored to individual circumstances and is based on the California Smokers' Helpline protocol [13]. It combines MI and cognitive-behavioral approaches to help clients change their behavior [13]. The initial session (intake session) focuses on evaluating their smoking history, their smoking patterns, and their motivation to quit. The counsellor's objectives are to address any ambivalence, reinforce self-efficacy and motivation, identify challenging situations, and establish coping mechanisms. Additionally, the counsellor and the participant agree on a quit date within a 14-day timeframe. Follow-up calls are offered for maintaining smoking cessation as well as relapse prevention and take place at different intervals after the quit date. For more detailed information, see the study protocol [30].

Self-help brochure

Participants in the control condition received a non-tailored self-help brochure titled 'Ja, ich werde rauchfrei!' ['Yes, I'll be smoke-free!'], provided by the Federal Centre for Health Education [31]. The 92-page booklet complies with the principles of CBT and directs readers through the process of quitting smoking and maintaining abstinence [18]. It covers topics such as understanding

smoking and quitting, preparing for cessation, and approaches to sustain abstinence (e.g., using coping techniques). The uptake of the brochure was self-directed. For more detailed information, see the study protocol [30].

Measures

Sample characteristics at baseline

At baseline, socio-demographic data including age, gender, nationality, employment status, marital status and living situation were assessed. Additionally, information on the years of smoking, cigarettes smoked per day, cigarette dependence (FTCD; [32]), numbers of quit attempts in the past, the most recent quit attempt, the use of smoking cessation aids of former quit attempts, the importance and confidence to quit (assessed on visual analogue scales ranging from 0 (not at all important/confident) to 100 (very important/confident)) and the presence of smoking-related chronic respiratory illnesses was gathered.

Use of the interventions

In the intervention group, participants were asked about the number of telephone counselling calls they had received (maximum six calls). In the control group, individuals reported whether they received the self-help brochure and, if so, the extent to which they had read it. Response options ranged from "very little", "less than half", "more than half" to "completely" [33].

Seven-day point prevalence abstinence

The primary outcome was the seven-day point prevalence abstinence (yes/no) at t_1. Individuals who had smoked cigarettes, even a single puff, or reported consuming any other type of tobacco products in the past seven days were classified as smokers.

Changes in smoking-related cognitions and coping strategies

The self-efficacy to refrain from smoking, positive smoking outcome expectancies, avoidance of external cues, and perceived control over withdrawal symptoms were assessed at t_0 and t_1.

Self-efficacy to refrain from smoking Participants were presented with twelve different situations, such as "When you are with friends who smoke" and were asked to rate the level of difficulty of refraining from smoking in each situation [25, 34, 35]. A 5-point Likert scale was used ranging from 1 (very easy) to 5 (very difficult). Values were recoded so that a higher mean score indicated higher self-efficacy to refrain from smoking. Cronbach's alpha was 0.82.

Positive smoking outcome expectancies Participants were requested to indicate their degree of agreement with ten statements related to smoking, such as "Smoking helps calming down", retrieved from the Pros of Smoking Scale [25, 36]. They provided their responses on a 5-point Likert scale, ranging from 1 (totally disagree) to 5 (totally agree). A lower mean score reflected a lower perception of smoking as being beneficial. Cronbach's alpha was 0.76.

Avoidance of external cues Participants were asked about the frequency of employing strategies to avoid external cues for smoking. Four items, such as "I remove things from my home that remind me of smoking" were used. These were rated on 5-point Likert scales ranging from 1 (never) to 5 (very often) and were derived from the stimulus control and counter-conditioning subscales of the Process of Change [25, 37]. A higher mean score indicated a greater utilization of strategies to avoid smoking-related external cues. Cronbach's alpha was 0.75.

Perceived control over withdrawal symptoms Perceived control over withdrawal symptoms was assessed using four items, such as "I believe that I am capable of dealing adequately with withdrawal symptoms from smoking" [38, 39]. Each statement was evaluated using a 5-point Likert scale, ranging from 1 (strongly disagree) to 5 (strongly agree). A higher mean score reflected a greater perception of control over withdrawal symptoms. Cronbach's alpha was 0.91.

Perceived effectiveness of intervention components and satisfaction with the intervention Participants in both study groups evaluated intervention components by indicating the helpfulness of the intervention regarding their motivation to quit/to maintain non-smoking, their management of withdrawal symptoms, their handling of strong cigarette cravings, their management of triggering situations, and their prevention of lapse/relapse [33]. Answer categories were "did not help", "helped a little", or "helped a lot". Additionally, participants expressed their level of satisfaction regarding the duration of the intervention ("too short", "about right", or "too long"). The overall satisfaction with telephone counselling/the self-help brochure was measured using the answer categories "very unsatisfied", "unsatisfied", "satisfied", or "very satisfied". Participants were further asked if they would recommend the intervention (yes/no) and about their willingness (yes/no) to use the telephone counselling services again if needed (intervention group only) [33].

Statistical analysis

Descriptive statistics (means, standard deviations and frequencies) were obtained for sample characteristics at baseline in the intention-to-treat (ITT) sample, which consisted of all randomized participants. The use of the intervention was described for individuals in the complete case (CC) sample, characterized by participants who received their allocated intervention and completed both questionnaires (t_0 and t_1). The ITT sample and the CC sample were compared in terms of baseline characteristics using unpaired *t*-tests and χ^2-tests. This approach was further employed to compare the treatment groups within both sample sets.

Abstinence was analyzed for the ITT and the CC sample. According to the Russell standard, participants with missing information on their smoking status were classified as smokers [40]. The odds ratios (*OR*s) and corresponding 95% confidence intervals (*CI*s) of abstinence (vs. non-abstinence) based on group assignment were examined using binary logistic regressions. The secondary outcomes could only be analyzed for the CC sample, which consists of participants who provided those data in the t_1 questionnaire. Mixed-repeated measurement Analyses of Variance (ANOVAs) were conducted to examine the impact of the intervention on changes in smoking-related cognitions and coping strategies. *Post-hoc* tests were performed using one-sided paired and one- (t_1) and two-sided (t_0) unpaired *t*-tests. To compare differences between groups in the perceived effectiveness of intervention components and the satisfaction with the intervention, χ^2-tests were applied. The significance level was set to $p=0.05$ for all statistical analyses. Data analyses were conducted using R version 4.3.0 [41, 42].

Results

Sample characteristics at baseline

A total of $n=905$ participants were randomized (ITT sample). Of those, $n=675$ completed the post-assessment (Fig. 1) and $n=653$ received their allocated intervention (CC sample). Descriptive statistics for baseline characteristics of the ITT sample are displayed in Table 1. No significant differences were observed for any of the assessed variables between the ITT and CC samples, for both the entire sample and the treatment groups. Additionally, no significant differences were found between participants in the intervention group and the control group in both sets of samples.

Attrition

To assess attrition, we conducted χ^2-tests for categorical variables and unpaired *t*-tests for continuous variables to compare baseline characteristics between participants lost to follow- up and those who completed the questionnaire at t_1. At t_1, $n=310$ participants (88.1%) completed the questionnaire in the telephone counselling group, while $n=365$ participants (85.3%) completed the questionnaire in the control group. There was no significant difference in attrition between study groups ($\chi^2(1)=1.06$, $p=0.303$). An analysis comparing participants lost at t_1 with those remaining on all baseline characteristics revealed a significant difference in German citizenship ($\chi^2(1)=6.06$, $p=0.014$). More participants without German citizenship were lost to follow-up compared to those with German citizenship. Additionally, participants lost at t_1 had a significantly higher daily cigarette use at baseline ($M=17.5$) compared to the remaining participants ($M=15.9$, $t(787)=2.07$, $p=0.039$). No significant differences were observed within the study conditions on the assessed variables.

Use of the interventions

Participants in the intervention group received on average 4.0 ($SD=1.6$, $R=1-6$) telephone counselling calls. Among individuals in the control condition, the majority read the brochure completely (56.9%) or at least half of it (31.0%). In total, 10.1% read less than half of the brochure and 2.0% read very little of the brochure.

Seven-day point prevalence abstinence

In the ITT sample, the intervention group demonstrated a higher seven-day point prevalence abstinence rate compared to the control group with rates of 41.1% vs. 23.1%, respectively. The odds for seven-day point prevalence abstinence were significantly higher ($OR=2.3$, 95% CI [1.7, 3.1]) for the intervention group in comparison with the control group. The CC sample yielded seven-day point prevalence abstinence rates of 63.9% in the intervention group and 28.4% in the control group. Significant higher odds ($OR=4.5$, 95% CI [3.2, 6.2]) for seven-day point prevalence abstinence were found for the intervention group compared to the control group.

Sensitivity analyses

To determine the robustness of the findings, abstinence was additionally defined as no use of any tobacco products or alternative products [43]. Moreover, we accounted for randomization strata and calculated adjusted and unadjusted *OR*s for abstinence. The findings remained consistent when considering abstinence from alternative products as part of the outcome or adjusting for randomization strata.

Changes in smoking-related cognitions and coping strategies

There was a significant group×time interaction effect on self-efficacy to refrain from smoking ($F(1, 651)=54.32$, $p<0.001$), positive smoking outcome expectancies ($F(1, 651)=23.52$, $p<0.001$), avoidance of external cues ($F(1,$

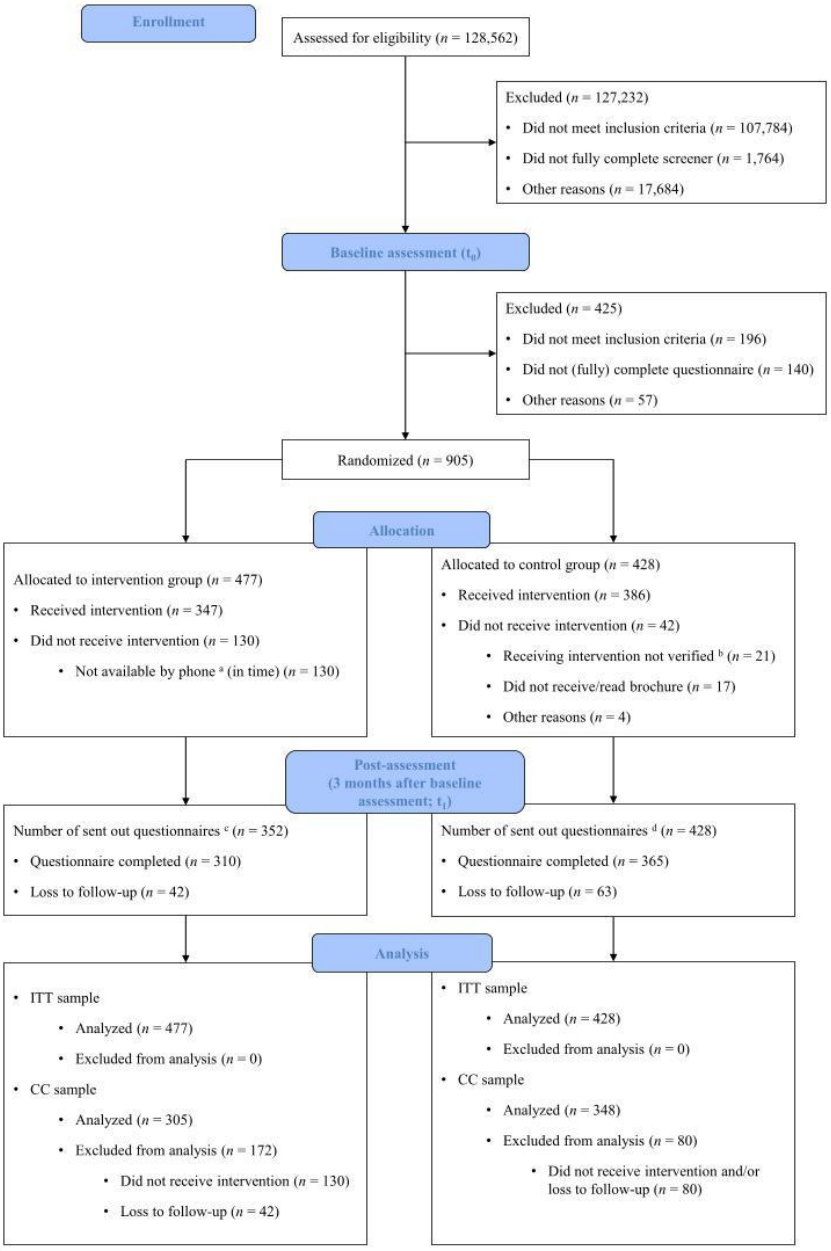

Fig. 1 Flowchart of participants

651)=10.74, p=0.001) and perceived control over withdrawal symptoms (F(1, 651)=40.44, p<0.001). No significant inter-group differences were found at baseline regarding the self-efficacy to refrain from smoking (t(651)=-0.48, p=1.00), positive smoking outcome expectancies (t(651)=-0.41, p=1.00), avoidance of external cues (t(651)=-1.46, p=0.291) and perceived control over withdrawal symptoms (t(651)=0.59, p=1.00). At post-assessment, the intervention group demonstrated significantly greater self-efficacy to refrain from smoking (t(651)=6.57, p<0.001), lower positive smoking outcome expectancies (t(651)=4.23, p<0.001), higher avoidance of external cues (t(651)=-4.98, p<0.001) and higher perceived control over withdrawal symptoms (t(651)=-6.05, p<0.001)

Table 1 Sample characteristics at baseline

Baseline characteristic	Full sample ($n=905$)	Intervention group ($n=477$)	Control group ($n=428$)
Age in years[a], *M* (*SD*)	42.8 (12.7)	42.5 (12.8)	43.3 (12.6)
Gender[a], *n* (%)			
Female	442 (48.8)	235 (49.3)	207 (48.4)
Male	462 (51.0)	241 (50.5)	221 (51.6)
Non-binary	1 (0.1)	1 (0.2)	-
German nationality[b], *n* (%)	873 (96.5)	459 (96.2)	414 (96.7)
Education[a,c], *n (%)*			
Low	163 (18.0)	88 (18.4)	75 (17.5)
Middle	261 (28.8)	137 (28.7)	124 (29.0)
High	481 (53.1)	252 (52.8)	229 (53.5)
Employment status, *n* (%)			
Unemployed	171 (18.9)	99 (20.8)	72 (16.8)
Casual	30 (3.3)	16 (3.4)	14 (3.3)
Part time	178 (19.7)	83 (17.4)	95 (22.2)
Full time	526 (58.1)	279 (58.5)	247 (57.7)
Marital status, *n* (%)			
Single	373 (41.2)	212 (44.4)	161 (37.6)
Married/Registered civil partnership	389 (43.0)	188 (39.4)	201 (47.0)
Divorced	132 (14.6)	72 (15.1)	60 (14.0)
Widowed	11 (1.2)	5 (1.0)	6 (1.4)
Living with a smoking partner[b], *n* (%)	283 (31.3)	144 (30.2)	139 (32.5)
Living with other smokers in a household[b], *n* (%)	103 (11.4)	55 (11.5)	48 (11.2)
Years of smoking, *M* (*SD*)	23.4 (12.9)	23.6 (13.3)	23.2 (12.5)
Cigarettes smoked per day[a], *M* (*SD*)	16.2 (7.7)	16.3 (8.1)	16.1 (7.4)
Nicotine dependence[c], *M* (*SD*)	3.9 (2.0)	4.0 (2.1)	3.8 (1.9)
Number of quit attempts in the past, *n* (%)			
None	95 (10.5)	48 (10.1)	47 (11.0)
One	93 (10.3)	41 (8.6)	52 (12.1)
Two	211 (23.3)	105 (22.0)	106 (24.8)
Three	175 (19.3)	95 (19.9)	80 (18.7)
Four	82 (9.1)	48 (10.1)	34 (7.9)
Five or more	249 (27.5)	140 (29.4)	109 (25.5)
Last quit attempt[d], *n* (%)			
Last week	22 (2.7)	9 (2.1)	13 (3.4)
2—3 weeks ago	53 (6.5)	25 (5.8)	28 (7.3)
More than 4 weeks ago	126 (15.6)	74 (17.2)	52 (13.6)
More than half a year ago	180 (22.2)	99 (23.1)	81 (21.3)
More than a year ago	429 (53.0)	222 (51.7)	207 (54.3)
Use of smoking cessation aids in attempt to quit/stay quit[b,d], *n* (%)	389 (48.0)	213 (49.7)	176 (46.2)
Importance to quit[e], *M* (*SD*)	86.6 (19.8)	86.5 (20.5)	86.8 (18.9)
Confidence to quit[e], *M* (*SD*)	60.8 (23.7)	60.3 (23.4)	61.3 (24.0)
Suffering from chronic respiratory illness[b], *n* (%)	145 (16.0)	75 (15.7)	70 (16.4)

[a] Used as a stratification variable

[b] Reflects the quantity and proportion of participants responding affirmatively

[c] Assessed with the Fagerström Test for Cigarette Depencence (FTCD)

[d] Only participants with a quit attempt in the past answered the question ($n_{\text{FullSample}}=810$, $n_{\text{ProactiveTelephoneCounselling}}=429$, $n_{\text{Self-helpBrochure}}=381$)

[e] Assessed on a Visual Analogue Scale with values ranging from 0 (not at all important/confident) to 100 (very important/confident)

compared to the control group. Significant intra-group differences from t_0 to t_1 were found in all the assessed psychological constructs for both groups (Table 2).

Perceived effectiveness of intervention components and satisfaction with the intervention

Compared with the control group, participants in the intervention group reported significantly higher perceived effectiveness of the intervention components: their motivation to quit, the management of their withdrawal symptoms, strong cravings, situations that trigger craving, and the prevention of lapse/relapse (Table 3).

Individuals in the intervention group expressed significantly higher satisfaction regarding both the intervention's duration and the overall intervention when compared to those in the control group (Table 4).

No significant differences between groups were found regarding the participants' recommendation of the intervention to others (intervention group = 84.9%, control group = 80.7%, $\chi^2(1) = 1.70$, $p = 0.193$). Additionally, 76.4%

Table 2 Means, standard deviations, and t-test statistics for changes in smoking-related cognitions and coping strategies

Smoking-related cognitions and coping strategies	Intervention group ($n = 305$)						Control group ($n = 348$)					
	Baseline		Post-assessment		$t(304)$	p	Baseline		Post-assessment		$t(347)$	p
	M	*SD*	*M*	*SD*			*M*	*SD*	*M*	*SD*		
Self-efficacy to refrain from smoking[a]	2.3	0.6	3.4	1.0	-19.14	< .001	2.4	0.6	2.9	0.8	-14.69	< .001
Positive smoking outcome expectancies[a]	2.8	0.5	2.3	0.6	12.96	< .001	2.8	0.5	2.5	0.5	9.32	< .001
Avoidance of external cues[a]	2.7	0.8	3.5	0.9	-11.60	< .001	2.6	0.9	3.1	0.9	-9.46	< .001
Perceived control over withdrawal symptoms[a]	3.2	0.9	3.9	1.0	-11.14	< .001	3.3	0.9	3.5	1.0	-3.59	< .001

[a] $R = 1–5$

Table 3 Frequencies and chi-square results for the perceived effectiveness of intervention components

Intervention component	Intervention group ($n = 305$)		Control group ($n = 348$)		χ^2		
	n	%	*n*	%	Value	*df*	*p*
Motivation to quit smoking/maintain non-smoking					50.09	2	< .001
Did not help	31	10.2	67	19.3			
Helped a little	123	40.3	200	57.5			
Helped a lot	151	49.5	81	23.3			
Management of withdrawal symptoms					26.11	2	< .001
Did not help	61	20.0	124	35.6			
Helped a little	154	50.5	166	47.7			
Helped a lot	90	29.5	58	16.7			
Management of strong cravings for cigarettes					23.67	2	< .001
Did not help	71	23.3	118	33.9			
Helped a little	145	47.5	180	51.7			
Helped a lot	89	29.2	50	14.4			
Management of situations that trigger strong cravings for cigarettes					28.51	2	< .001
Did not help	70	23.0	112	32.2			
Helped a little	126	41.3	175	50.3			
Helped a lot	109	35.7	61	17.5			
Prevention of lapse or relapse					58.54	2	< .001
Did not help	74	24.3	156	44.8			
Helped a little	120	39.3	148	42.5			
Helped a lot	111	36.4	44	12.6			

Table 4 Frequencies and chi-square results for the satisfaction with the intervention

	Intervention group		Control group		χ^2		
	(*n* = 305)		(*n* = 348)				
	n	%	*n*	%	Value	*df*	*p*
Satisfaction with the length of the intervention, %					24.60	2	< .001
Too short	16	5.2	37	10.6			
About right	269	88.2	253	72.7			
Too long	20	6.6	58	16.7			
Overall satisfaction with the intervention, %					54.58	3	< .001
Very unsatisfied	27	8.9	16	4.6			
Unsatisfied	27	8.9	50	14.4			
Satisfied	133	43.6	227	65.2			
Very satisfied	118	38.7	55	15.8			

of individuals in the intervention group expressed their willingness to contact the quitline again if needed.

Discussion

The present study examined the short-term effectiveness of the national German quitline for smoking cessation using a two-arm RCT comparing the counselling services to a self-help brochure. As expected, proactive telephone counselling outperformed the support of a self-help brochure, with a greater likelihood of seven-day point prevalence abstinence three months from baseline. The telephone counselling's superiority may be attributed to its ability to provide personalized support tailored to an individual's specific requirements [10, 13] in contrast to a non-tailored self-help brochure. Moreover, although the self-help brochure also followed CBT principles, CBT has been demonstrated to yield more substantial effects when supplemented with guidance, for example from a counsellor [44, 45]. Lastly, a comprehensive approach that combines elements of CBT and MI has been shown to be more effective in supporting smoking cessation compared to solely using CBT [46].

The current result aligns with prior research, indicating that proactive telephone counselling for smoking cessation yields greater abstinence rates when compared to minimal intervention controls [10]. However, the present smoking cessation rates in both conditions were higher than those in previous studies [10, 21, 47]. For example, the European Smoking Cessation Helplines Evaluation study (ESCHER) focused on evaluating national quitline usage and its impact on smoking cessation rates across multiple European countries [21]. Across countries, an overall seven-day point prevalence abstinence rate of 14.3% was reported among individuals who were preparing to quit and received quitline counselling. Regarding the effectiveness of printed self-help resources for smoking cessation, a meta-analysis demonstrated abstinence rates ranging from 2 to 10% [47].

The disparity in cessation rates in comparison with previous studies might be explained by the time-point of abstinence assessment and the included samples. Compared to the three-month post-assessment in the current study, previous studies [10, 21, 47] evaluated abstinence at least six months after the intervention. Although relapses are most common within the first five to ten days of a quit attempt, they are still likely to occur in the following months [48]. Abstinence rates for both groups in the present study are therefore expected to decrease over time. The difference in abstinence rates between the current study and previous research might also be attributed to differences in the study samples. In the current study, participants were eligible to participate if they intended to quit smoking within the next four weeks. This eligibility criterion was less strict in prior research [10]. However, the intention to quit smoking was identified as a predictor of quit attempts [49, 50], possibly explaining the higher abstinence rates in the current study.

As expected, both study groups demonstrated significant enhancements in smoking-related cognitions and coping strategies. Nevertheless, individuals who received quitline counselling reported greater self-efficacy to refrain from smoking, less positive smoking outcome expectancies, higher avoidance of external cues and higher perceived control over withdrawal symptoms than participants who read the self-help brochure. Those greater enhancements in the telephone group may be attributed to the structured, individually tailored counselling using evidence-based elements of CBT and

MI targeting those psychological processes. However, the content of the brochure was also based on elements of CBT, possibly explaining the found improvements in the control condition over time. By including CBT-based strategies like cognitive reorganization to target unhelpful thought patterns, the content of the brochure intended to target the same psychological processes.

The same pattern of results was found regarding the participants' perceived effectiveness of intervention components and their satisfaction with the intervention. In both groups, more than half of the participants perceived the intervention components as at least a little helpful with regard to their motivation to quit, their ability to manage withdrawal symptoms, their ability to manage strong cravings for cigarettes and situations that trigger strong cravings, as well as with their ability to prevent lapses or relapses. However, the individuals in the telephone counselling condition perceived the intervention as more helpful and were more satisfied with the intervention than the participants in the control condition.

This study holds significant implications. Of German smokers making an annual attempt to quit smoking (19.9%), only 13.0% use evidence-based strategies [51]. While methods like brief consultations with physicians and over-the-counter nicotine replacement therapy are used most often (5.3% and 4.9%, respectively), merely 0.8% of individuals turn to quitlines for support [51]. Given the short-term effectiveness of the German national quitline for smoking cessation and its potential for long-term effectiveness, future research should investigate the factors that contribute to its underutilization.

Literature suggests that barriers to smoking cessation treatments possibly include the cost of treatment, a lack of awareness regarding the availability of cessation support and a reduced interest in conventional approaches [52–54]. As the national German quitline for smoking cessation offers telephone counselling free of charge, the cost of treatment does not constitute a barrier in Germany. However, future research needs to examine smokers' awareness of the existence of the national quitline and its services and possibly increase its promotion or adapt promotion strategies.

A reduced interest in conventional smoking cessation interventions and a personal preference for a certain type of intervention emphasize that telephone counselling should supplement other forms of smoking cessation counselling. The results of the current study confirm that quitline counselling should be an important part of public health provision [20]. While quitlines may produce lower abstinence rates compared to clinical interventions, as a public health approach, they can cast a wider net to reach a larger number of smokers [20, 55] and, therefore, may have a greater potential to reduce rates of morbidity and mortality [56]. Considering that evidence-based treatments provided through national quitlines have been well-established in alternative formats, such as face-to-face individual or group therapy for smoking cessation [20, 57, 58], quitline counselling should be one element in a comprehensive stepped-care strategy of smoking cessation support. To accommodate the diverse needs and preferences of smokers, a range of support options should be available, offering varying levels of intensity and degrees of anonymity.

The results presented are subject to limitations. First, the present sample differs from callers to the national German quitline for smoking cessation and recipients of pro-active follow-up calls with regard to socio-demographic and smoking-related variables [59]. Consequently, the external validity of the results is somewhat limited. Although this could have been accounted for by including only individuals in the study who called the quitline, randomizing callers to the control condition would have been ethically inappropriate. Second, using self-reported data to assess abstinence may have led to an overestimation of actual abstinence rates [60]. Nevertheless, biochemical validation in smoking cessation research may not be necessary and the misrepresentation of the smoking status is considered rare [61]. Third, the current study examined the short-term effectiveness of telephone counselling services. However, evidence on the long-term effectiveness is needed to ascertain sustainability of the treatment effects [40]. Results on whether the counselling services of the national German quitline for smoking cessation leads to long-term abstinence will be published once data analysis is completed.

This study demonstrates that the national German quitline for smoking cessation is effective in the short term. In addition to the high abstinence rates, the positive changes in intervention targets and the participants' satisfaction with the telephone counselling highlights the potential of the provided services to curb smoking addiction and reduce the associated burden of disease. The present findings carry implications for public health policy, indicating that the availability and the promotion of telephone counselling services could serve as a valuable strategy for augmenting smoking cessation initiatives in Germany.

Abbreviations

ANOVA	Analysis of Variance
BZgA	Bundeszentrale für gesundheitliche Aufklärung, Federal Centre for Health Education
CBT	Cognitive behavioral therapy
CC	Complete case
CI	Confidence interval

CONSORT	Consolidated Standards for Reporting Trials
DGP	Deutsche Gesellschaft für Psychologie, German Psychological Society
DRKS	Deutsches Register klinischer Studien
FCTC	Framework Convention on Tobacco Control
FTCD	Fagerström Test for Cigarette Dependence
IFT	Institut für Therapieforschung
ITT	Intention-to-treat
MI	Motivational interviewing
RCT	Randomized controlled trial
RR	Risk ratio
WHO	World Health Organization

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Authors' contributions
SD, KL and LK designed the study. SD, SM, KL and LK did the conceptional work. SM and SD conducted the statistical analyses. SM wrote a first draft of the manuscript. SD, KL, LK, EH, OP and JB revised the manuscript. All authors approved the final version of the manuscript for publication.

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Availability of data and materials
Anonymized study data and statistical codes to analyses may be made available on request from the corresponding author following study closure.

Declarations

Ethics approval and consent to participate
This study has been approved by the Ethics Committee of the German Psychological Society (DGP). It follows the Consolidated Standards of Reporting Trials (CONSORT; [62]) and complies with the principles stipulated in the Declaration of Helsinki [63]. The study is registered in the German Clinical Trials Register (DRKS) public database (trial registration number DRKS00025343, date of registration: 2021/06/07). All substantial protocol deviations or modifications were communicated to the Ethics Committee and the DRKS. Upon enrollment, participants provided written informed consent. The consent form will be provided on request.

Consent for publication
Not applicable. The study results will be presented at conferences and will be submitted for publication in relevant journals.

Competing interests
The authors declare no competing interests.

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Long-term Effectiveness of a Quitline for Smoking Cessation: Results of a Randomized Controlled Trial

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Abstract

Introduction: Smoking remains a significant global public health issue, leading to numerous preventable deaths and disabilities annually. Telephone counselling is a recommended intervention for smoking cessation, offering accessible support to a wide range of people who smoke. This study aimed to evaluate the long-term effectiveness of the German quitline for smoking cessation.

Methods: A parallel-group, two-arm, superiority, randomized controlled trial was conducted between October 2021 and November 2023. People who smoked daily and were willing to quit, received either up to six telephone counselling calls (intervention group) or a self-help brochure (control group). Seven-day point prevalence abstinence from cigarettes and tobacco at 12 months and prolonged cigarette and tobacco abstinence from 3 to 12 months after the start of the intervention were assessed. Further, the use of additional cessation aids was assessed.

Results: A total of $n = 905$ participants were randomized (intention-to-treat sample). The intervention group ($n = 477$) exhibited higher rates of prolonged cigarette abstinence (31.7% vs. 17.8%) and prolonged tobacco abstinence (30.8% vs. 15.2%) compared to the control group ($n = 428$) at 12-month follow-up with corresponding odds ratios of 2.2 (95% CI [1.6, 3.0]) and 2.5 (95% CI [1.8, 3.5]). Seven-day point prevalence cigarette abstinence was not statistically significant ($OR = 1.3$, 95% CI [1.0, 1.7]). E-cigarettes were the most commonly used additional cessation aid (46.0%), followed by electronic media (31.0%) and nicotine replacement therapy (26.2%).

Conclusions: Telephone counselling provided by the national German quitline for smoking cessation demonstrates effectiveness in promoting long-term abstinence from cigarettes and tobacco. Increased awareness and use of the quitline could promote cessation rates in Germany. Given the rising popularity of novel nicotine consumer

products, counselling protocols should incorporate information on their risks and potential as cessation tools.

Plain Language Summary

Smoking is a major global health problem, causing many preventable deaths and disabilities each year. Telephone counselling is a recommended method to help people quit smoking because it provides accessible support. This study examined the long-term effectiveness of the national German Smokers Quitline. Daily smokers who wanted to quit smoking were divided into two groups. One group received up to six phone calls from the national German Smokers Quitline, the other group received a self-help brochure. We measured how many participants stopped smoking for at least 7 days 12 months after the start of the intervention (7-day point prevalence of abstinence). We assessed long-term cigarette and tobacco abstinence, i.e., how many participants abstained from cigarettes/tobacco for a period of 9 months after the start of the intervention. We also examined the use of other cessation aids. A total of 905 participants took part in the study. The telephone counselling group had higher rates of long-term cigarette (31.7% vs. 17.8%) and tobacco abstinence (30.8% vs. 15.2%) compared to the other group. The odds of quitting were significantly higher in the telephone counselling group. However, the 7-day point prevalence of abstinence did not differ between the groups. Many participants used additional cessation aids, with e-cigarettes being the most common. In conclusion, telephone counselling provided by the national German Smokers Quitline is effective in helping people quit smoking long-term. Increasing its awareness could improve smoking cessation rates in Germany. Counselling should include information about the risks and benefits of new nicotine consumer products.

Introduction

Smoking remains the leading cause of preventable diseases, disabilities, and deaths worldwide. In 2019, worldwide 7.69 million people died due to tobacco consumption and the burden of disease counted 200 million disability-adjusted life years (DALYs) indicating a great toll on public health [1]. To reverse the negative impact of smoking on health, prevention efforts are not enough [2]. For a decrease in mortality due to smoking, a variety of evidence-based cessation treatments need to be made available to people who smoke [3]. One effective smoking cessation treatment proposed by the World Health Organization's Framework Convention on Tobacco Control (WHO FCTC) is the implementation of telephone counselling services (quitlines) [2]. Trained specialists effectively assist individuals in their efforts to quit smoking by telephone [4].

Telephone counselling for smoking cessation has the potential to reach a large number of people who smoke [5]. Due to its independence in time and location, telephone counselling is attractive to individuals who cannot attend therapy physically [6], who need immediate cessation support [7], and who seek low threshold support with therapist contact [8, 9]. Telephone counselling can also offer treatment to underserved groups, such as ethnic and/or linguistic minorities [10, 11]. Another advantage of telephone counselling is the possibility to provide individualized treatment and to tailor the intervention to characteristics of the recipient. In a recent meta-analysis, including 104 trials and 111,653 individuals, telephone counselling was found to be 1.38 times more effective than self-help materials in promoting long-term abstinence [4], increasing the likelihood from 7% to 10%. Although telephone counselling has been shown to reach lower abstinence rates than face-to-face counselling, quitlines can be considered a measure with major public health potential [12].

The effectiveness of quitlines has been shown in previous studies [4], but the rapidly growing market and the increased use of novel nicotine consumer products throughout the past years [13], require their consideration when ascertaining nicotine and tobacco use status in clinical trials [14, 15]. In Germany, the use of novel products is widespread. E-cigarette use in the past 30 days was reported by 4.3% (2.2 million) German adults and heat-not-burn product (HNB) use by 1.3% (665,000) of the German adult population [16].

The national German Smokers Quitline was implemented in 1999 and is overseen by the Federal Centre for Health Education [17]. Results on the short-term effectiveness of the national German Smokers Quitline were recently reported elsewhere [18]. Participants who received telephone counselling had statistically significant higher 7-day point prevalence abstinence (PPA) rates (3 months from baseline) than participants who received a self-help brochure (41.1% vs. 23.1%; *OR* = 2.3, 95% CI [1.7, 3.1]) [18]. Investigating the long-term effectiveness of the German quitline for smoking cessation will provide important information for German tobacco control policies and will have implications for the German prevention landscape. It is important to understand the magnitude of cessation aids used next to telephone counselling provided by the German quitline as it informs about possible adaptions to the counselling protocol due to emerging trends in consumer products.

The objective of the present study was to examine the long-term effectiveness of the national German Smokers Quitline. Using a two-arm randomized controlled trial (RCT), we compared abstinence rates between participants who had received proactive telephone counselling and those who had received a self-help brochure (active control condition) 12 months from baseline. Based on former research [4], we hypothesized that the telephone counselling group would exhibit higher abstinence rates compared to the control group. To address the emergence of novel consumer products [13], we used two

definitions: cigarette abstinence and tobacco abstinence. As recommended by the SRNT network [15], we assessed abstinence from combustible cigarettes to enable comparisons with previous studies. Additionally, as a more conservative measure, we assessed abstinence from all combustible and smokeless tobacco products, such as cigars, pipes, snus, or HNB. Further, we examined differences between the study groups in the number and type of additionally used cessation aids, as different use across study groups may have influenced the effect sizes of abstinence.

Methods

Study Design

A parallel-group, two-arm, superiority, randomized controlled trial design was used. Participants were stratified and randomly assigned to either the intervention group receiving telephone counselling or the control group receiving a self-help brochure [19]. Data was collected at baseline (t_0), 3 months (t_1) and 12 months (t_2) after baseline assessment.

Study Procedure

Smokers residing in Germany were recruited via an online access panel, social media, and in person from October 2021 to July 2022. To be eligible for participation, participants had to (1) be at least 18 years old, (2) have smoked cigarettes daily in the past month, (3) intend to quit smoking in the following month, and (4) give informed consent. Upon completing the online baseline survey at t_0, participants were randomly assigned to either the intervention or control group. Randomization (1:1 allocation ratio) was stratified for number of cigarettes smoked per day (*1-10/11-20/21-30/> 30 cigs per day*), sex (*female/male/diverse*), age (*18-30/ 31-64/> 64 years old*), and level of education (*low/middle/high*). Allocation concealment was ensured, as participants were not

assigned to study conditions until baseline measurements were completed. Neither participants nor staff were blinded to allocation. Participants were informed about the two study conditions but were blinded to the study hypothesis regarding which intervention was considered active. For detailed information, see the study protocol [20].

After randomization, participants were notified via email about their group assignment and started the corresponding intervention within 2 weeks at most. In the intervention group, participants were contacted by telephone counsellors to initiate the intervention (up to 3 times), while in the control group, the study team confirmed receiving the self-help brochure through phone calls. After 3 and 12 months, participants were emailed the online post- and follow-up-questionnaire. Participants who did not respond, received two reminder emails and a phone call from the study team to encourage completion. Participants could earn up to EUR 55 for completing all questionnaires and additionally entered a lottery with a prize of EUR 50. Participants in the control condition were offered telephone counselling after data collection was completed. The study was finalized in November 2023.

Interventions

Telephone Counselling Condition

The national German Smokers Quitline provides telephone counselling to smokers, former smokers facing relapse, and information seekers. The counselling follows a structured protocol based on the protocol of the California Smokers' Helpline [6]. This approach is rooted in the theory of social learning [21, 22], combining the principles of motivational interviewing [23] and those of cognitive behavioural therapy (CBT) [6, 24]. Participants received up to six telephone counselling calls across approximately 6 weeks. The counselling protocol [6, 17] covers two phases of smoking cessation: preparing to quit (first session) and the maintenance of smoking cessation and relapse prevention after

quitting (up to five sessions). The intake session focused on evaluating the client's smoking history, smoking habits, and motivation to quit. Clients were encouraged to set a quit date within 14 days. The follow-up calls aimed to evaluate coping strategies, to discuss withdrawal symptoms and craving, as well as to address challenging situations after quitting.

Self-Help Condition

In the control condition, participants received a non-tailored self-help brochure titled ‘Ja, ich werde rauchfrei!’ [‘Yes, I’ll be smoke-free’] which is distributed by the Federal Centre for Health Education (https://shop.bzga.de/ja-ich-werde-rauchfrei-31350000/) [19]. The 92-page booklet adheres to the principles of CBT and leads the reader from preparing to quit to sustaining long-term abstinence. The uptake of the brochure was self-directed.

Measures

Sample Characteristics

Socio-demographic data (age, gender, nationality, employment status, marital status and living situation) and the presence of chronic respiratory illnesses were gathered at baseline. Smoking-related variables were assessed, including the years of smoking, number of cigarettes smoked per day, cigarette dependence (FTCD) [25], number of past quit attempts, time of the most recent quit attempt, the use of smoking cessation aids in former quit attempts, the importance and confidence to quit (visual analogue scales ranging from 0 (*not at all important/confident*) to 100 (*very important/confident*)).

Cigarette Abstinence

We assessed (1) 7-day PPA (*yes/no*) at t_2 and (2) prolonged abstinence (*yes/no*) at t_2 from cigarettes. Smokers were defined as (1) individuals who had smoked cigarettes, even a

single puff, in the past seven days or as (2) individuals who had smoked within the last 9 months (allowing up to 5 cigarettes in total). According to the Russell standard criteria (RS) [26], participants with unknown smoking status were considered smokers. The 7-day PPA and the prolonged abstinence from cigarettes were the primary outcomes in this study as described in the study protocol [20].

Tobacco Abstinence

Additionally we assessed (3) 7-day PPA (*yes/no*) at t_2 and (4) prolonged abstinence (*yes/no*) at t_2 from tobacco, as recommended by the SRNT network. [15] Smokers were defined as (3) individuals who had smoked cigarettes, even a single puff, or reported consuming any other type of tobacco products in the past seven days or as (4) individuals who had smoked within the last 9 months (allowing up to 5 cigarettes in total) or reported consuming any other type of tobacco products.

Quit Attempts and Use of Cessation Aids

Occurrence of quit attempts (defined as at least 24 hours of self-reported abstinence) was assessed at t_2 by asking “how often have you tried to quit smoking in the past 9 months?” [27]. Participants who reported at least one quit attempt were asked "have you used any of the following aids to support smoking cessation in the past 9 months?" (a list was provided and additional open entry was possible; see Table 1). E-cigarette users were also asked about the nicotine content of the used e-cigarette (*with nicotine/without nicotine/with and without nicotine*).

[Table 1]

Statistical Analyses

Descriptive statistics were obtained for socio-demographic variables, smoking-related variables, and the presence of chronic respiratory illnesses at t_0 in the intention-to-treat

(ITT) sample, which included data from all randomized participants [26]. Previous analyses showed that these characteristics were equally distributed between the two study groups at t_0 [18].

Abstinence measures were analyzed for both, the ITT and the complete case (CC) sample, which included only treated participants with data from all assessments. Using binary logistic regression models, we compared cigarette and tobacco abstinence rates between the two groups and computed odds ratios (*OR*) with 95% confidence intervals (CIs), respectively.

Use and adherence of cessation aids were analyzed for the CC sample. Descriptive statistics were used to describe these variables. To examine group differences, χ^2-tests were conducted.

All statistical analyses were performed using R version 4.2.2 [28], with the significance level set at $\alpha = .05$. To calculate the required sample size, an a priori power analysis was conducted using the software G*Power [29]. Based on previous research [4] a small effect size was expected (Cohen's $d = 0.3$). Assuming a significance level of 0.05 and statistical power of 0.8, the estimated sample is $n = 700$ participants. The calculated sample size was corrected by a 30% dropout rate at t_2 [30], resulting in a total sample size of $n = 910$ participants.

Results

Sample Characteristics

A total of $n = 905$ participants were randomized (ITT sample; shown in Fig. 1). Of those, $n = 613$ received the allocated intervention and completed the post and follow-up assessment (CC sample). In the intervention group, nearly one-third ($n = 130$) of the

randomized participants did not receive the intervention, whereas this was the case for about 10% (n = 42) of the randomized participants in the control group.

[Figure 1]

In the ITT sample, participants were on average 42.8 years old (SD = 12.7; shown in Table 2). Thereof, 48.8% were female, 51.0% male, and 0.1% non-binary individuals. Most participants (96.5%) were of German nationality. Low education was reported by 18.0%, medium level education by 28.8%, and a high level by 53.1%. On average, participants had smoked for 23.4 years (SD = 12.9), smoked 16.2 cigarettes per day (SD = 7.7) and were moderately nicotine dependent (mean FTCD score = 3.90, SD = 2.0). No statistically significant differences were observed in any of the assessed variables between the ITT and the CC sample.

[Table 2]

To assess attrition, we conducted χ^2-tests for categorical variables and unpaired t-tests for continuous variables to compare baseline characteristics between participants lost to follow-up and those who completed the questionnaire at t_2. At t_2, n = 310 participants (88.1%) completed the questionnaire in the telephone counselling group, while n = 355 participants (82.9%) completed the questionnaire in the control group ($\chi^2(1) = 4.04$, $p < .05$). An analysis comparing participants lost at t_2 with those remaining on all baseline characteristics revealed no statistically significant differences. Further, no statistically significant differences were observed within the study groups on the assessed variables.

Abstinence

Logistic regression analyses showed that in both, the ITT and CC sample, the intervention group outperformed the control group in reaching cigarette and tobacco abstinence at t_2 with the exception of 7-day point-prevalence cigarette abstinence in the ITT sample

(*OR* = 1.3, 95% CI [1.0, 1.7]; shown in Table 3). In the CC sample participants in the intervention group were more than twice as likely to achieve 7-day point-prevalence cigarette abstinence (*OR* = 2.3, 95% CI [1.6, 3.1]). For prolonged cigarette abstinence, the *OR*s were 2.2 (95% CI [1.6, 3.0]) in the ITT sample and 3.6 (95% CI [2.6, 5.2]) in the CC sample, respectively.

[Table 3]

Sensitivity Analyses

We ran two additional analyses on the abstinence outcomes to test the robustness of the findings. First, we controlled for randomization strata. Adjusted and unadjusted *OR*s demonstrated no or minimal differences. Second, no contamination effect [31] was identified either when participants of the control group who received additional telephone counselling (n = 12) were excluded from the analyses, or when participants of the intervention group, who additionally read the brochure (n = 29) were excluded.

Use of Additional Cessation Aids

At t_2, 90.4% (n = 554) of the participants reported at least one quit attempt during the last 9 months. There were no statistically significant differences between the two groups in terms of the occurrence of quit attempts ($\chi^2(5) = 1.91$, $p = .752$).

In total, 439 participants (71.6% of the CC sample) used additional cessation aids (shown in Table 1). Alongside with the respective intervention, e-cigarettes were the most commonly used cessation aid (46.0%), followed by electronic media (31.0%) and nicotine replacement therapy (NRT) (26.2%). With 34.4%, statistically significant more participants in the intervention group used NRTs than in the control group (20.2%; $\chi^2(1) = 3.85$, $p = .050$). No statistically significant differences between groups were

observed in the combination of NRT use or in the use of any other additional cessation aid.

Discussion

The current study examined the long-term effectiveness of the national German Smokers Quitline using a two-arm randomized controlled design with baseline, post and follow-up assessments. In the intervention group, participants received counselling from the national German Smokers Quitline, while in the control condition, they received a self-help brochure to support smoking cessation. Also, the study provides a comprehensive overview of additionally used cessation aids to account for the effect of possible group differences on abstinence.

As expected, our findings confirm the long-term effectiveness of proactive telephone counselling in demonstrating 9-month prolonged cigarette and tobacco abstinence at 12-month follow-up. Overall, participants in the ITT sample were found to be twice as likely to report 9-month prolonged abstinence at 12-month follow-up than participants in the control group and about 4 times more likely in the CC sample. The prolonged abstinence rates in the current study were higher than those reported in former research (ranging from 4% to 15%) [4, 32, 33]. The disparity in prolonged abstinence rates may be explained by differences in sample characteristics, especially participants' motivation to quit. Participants of the current study had to intend to quit smoking within the next 4 weeks. Participants in previous studies varied with regard to their stages of change and motivation to quit has not always been an inclusion criterion [4]. As the intention to quit smoking has been identified as a predictor of quit attempts [34, 35], it might explain the higher abstinence rates in the current study.

Unexpectedly, the 7-day PPA at t_2 showed statistically non-significant effects for cigarette abstinence ($OR = 1.3$, 95% CI [1.0, 1.7]) and small effects for tobacco

abstinence. This might be partly explained by the relatively high abstinence rate (30.1%) among participants who received the self-help brochure. A previous meta-analysis reported substantially lower abstinence rates ranging from 2% to 10% in smoking cessation trails using printed self-help materials [33]. In this study, the 7-day PPA rate increased in the control group by 5.4 percentage points in the ITT sample (6.7 in the CC sample, respectively) from the 3-month [18] to 12-month assessment. High intention to quit may have led to a high engagement with the self-help material [36]. Research has shown a linear dose effect on treatment intensity on abstinence [37, 38]. This is supported by the fact, that in this study the re-use of the self-help brochure after the 3-month assessment was 3 times higher than the re-use of telephone counselling. In addition, the protocol of this study with intensive (personal) follow-ups could have increased abstinence rates in the control group. In previous research, participants reported feeling motivated to remain smoke-free knowing that they would be contacted by a researcher [36]. Finally, the two study groups substantially differed in the number of participants who did not receive the intervention [39]. In the intervention group, 3 times more participants did not receive the intervention which might have led to an underestimation of the superiority of telephone counselling.

We observed only minimal differences between cigarette and tobacco abstinence. While telephone counselling might demonstrate slightly higher effectiveness in achieving tobacco abstinence compared to cigarette abstinence, further research is needed to understand this difference and its underlying factors.

Overall, about two-thirds of the participants used at least one additional cessation aid. Among these, significantly more respondents of the intervention group used NRTs (34.4% vs. 20.2%). Research has shown that quitline counselling increases the use of NRTs [4]. This might explain the higher proportion of NRT users in the intervention

group, given that the recommendation of NRT use is part of the counselling protocol of the German quitline. The use of other additional aids, such as e-cigarettes, electronic media, medical advice, HNB or medication did not significantly differ between the two study groups. Thus, we assume that the use of additional cessation aids did not influence the effect sizes of abstinence.

Consistent with previous research on the use of cessation aids [40], e-cigarettes, with or without nicotine, were the most commonly used additional cessation aid in the present study, used by approximately one-third of the participants (n = 202). There is research showing that e-cigarette use increases adult smoking cessation [41]. E-cigarettes with nicotine seem to lead to higher quit rates than the use of e-cigarettes without nicotine [42]. However, a meta-analysis of four studies showed that e-cigarettes were also associated with the development of lasting nicotine dependence [43]. This calls for a balanced consideration of the recommendation to use e-cigarettes as a tool for smoking cessation [44].

Among participants who used additional cessation aids, only a few used medications to support smoking cessation (3.4%), although 15% of participants sought additional medical advice. The low use of medications is in line with former research [45] and could be explained by the requirement for medication to be prescribed by a general practitioner. German representative data from 2016 to 2019 showed that only 2% of people who smoke were recommended to use medication (or NRTs) by their primary care physician [46], possibly due to the lack of reimbursement of treatment costs [45]. However, a combination of behavioural and pharmacological treatment enhances cessation rates [47].

Implications

The current study indicates the effectiveness of the national German Smokers Quitline. In a stepped-care approach, quitline counselling can be considered an evidence-based

strategy to reduce tobacco use, which should be continuously offered to German smokers among a variety of other smoking cessation treatments. The 30-day prevalence of tobacco use in Germany was estimated at 22.7% (11.6 million people who smoke) in 2021 [16]. Only 13.0% of German smokers who tried to quit at least once (19.9%) in 2019 employed an evidence-based approach in their efforts to quit [45]. In 2023, about 23,000 people who smoke contacted the German Smokers Quitline seeking cessation support. Future research needs to investigate the awareness of the quitline and its program among smokers. Increasing its awareness through targeted communication campaigns could expand call volume and might therefore have a greater impact on smoking rates in Germany.

Most participants used additional cessation aids. Counselling protocols for quitlines need to take the emerging trend of novel nicotine consumer products into account, especially those containing nicotine. Foremost, counsellors should assess callers' usage of additional products. Regarding the use of e-cigarettes, callers need to be informed about both the relative health risks of vaping and smoking and its potential to support smoking cessation [44]. Studies suggest that vaping is likely less harmful than smoking combustible tobacco cigarettes [48, 49], however, a large number of German smokers consider vaping nicotine just as harmful as or more harmful than cigarette smoking [50]. Individuals unable to quit smoking with evidence-based cessation methods [51] should understand the potential vaping might have to help them quit smoking [44]. As vaping comes with health risks and its long-term health consequences are still unknown, completely transitioning likely reduces health risks [49], but vaping should eventually be stopped as well. Carefully considered, e-cigarette use among smokers wanting to quit smoking can reduce adult smoking and therefore benefit public health and play a role in harm reduction [51].

Limitations

This study is not without limitations. We applied the RS criteria for smoking cessation trials [26], which enhanced the quality and generalizability of the data. However, the lower effect sizes in the ITT samples compared to the CC samples are likely influenced by the substantial discrepancy between the two study groups in the number of participants who did not receive the intervention [39]. Using the conservative imputation approach according to the RS [26], these participants were classified as non-abstainers, potentially underestimating the effectiveness of telephone counselling. Moreover, relying on self-reported data for the assessment of abstinence might have resulted in an overestimation of actual abstinence rates [52]. Biochemical validation was planned for this study [20], but it turned out to not be feasible because participants were spread all over Germany, making it impossible to form regional clusters for data collection. However, the occurrence of misrepresentation of the smoking status in cessation trials is generally considered rare [14].

Conclusions

Telephone counselling provided by the national German Smokers Quitline is shown to be effective and therefore serves as a valuable strategy for reducing smoking prevalence in Germany. Future research needs to investigate whether and how the awareness of the national German Smokers Quitline can be increased to enlarge call volume. Counselling protocols for quitlines should take novel nicotine consumer products into account and inform callers about their health risks and possibilities as smoking cessation tools.

Statements

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Statement of Ethics

This study has been approved by the Ethics Committee of the German Psychological Society (DGPs; reference: KrausLudwig2021-03-15VA). It follows the Consolidated Standards of Reporting Trials (CONSORT) (1). It complies with the principles stipulated in the Declaration of Helsinki (2). The study was registered in the DRKS public database (trial registration number: DRKS00025343; https://www.drks.de/drks_web/setLocale_EN.do). All substantial protocol deviations or modifications were communicated to the DRKS. Upon enrolment, participants provided written informed consent. The consent form will be provided on request.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

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Author Contributions

S.D., L.K. and K.L. designed the study. S.D., S.M., L.K. and K.L. did the conceptional work. S.D. and S.M. did the data collection and management. SD conducted data

cleaning, ran the analysis, and wrote a first draft of the manuscript. S.M., L.K., O.P., E.H. and K.L. revised the manuscript. All authors approved the final version of the manuscript for publication.

Data Availability Statement

The data that support the findings of this study are not publicly available due to its size and complexity, as well as to ensure proper usage and interpretation but are available from the corresponding author upon reasonable request.

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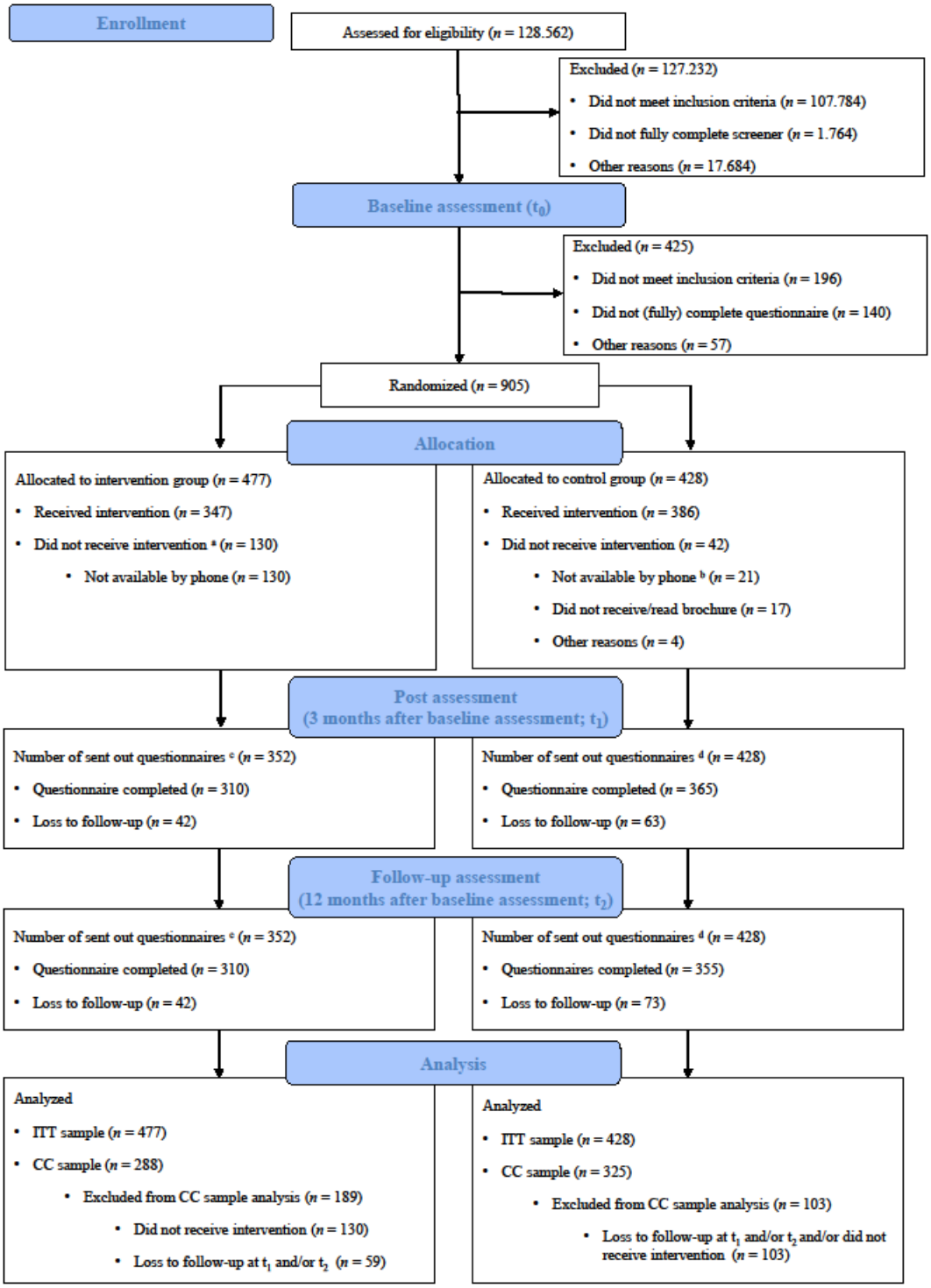
Fig. 1. Flowchart of participants



Note. ITT = intention-to-treat; CC = complete case.
[a] Three call attempts by the hotline not accepted. [b] Five call attempts by the study team not accepted. [c] Participants, who received the intervention (n = 347) and participants who were later classified as not having received the intervention (n = 5) were assessed. [d] All randomized participants were assessed.

Table 1. *Use of additional cessation aids in total and by group*

Cessation aid used[a]	**Total**	**Telephone counselling**	**Self-help brochure**	**Statistical difference χ^2**		
	***n* = 439**	***n* = 186**	***n* = 253**			
	% (*n*)	**% *(n)***	**% *(n)***	**Value**	***df***	***p***
E-cigarette	46.0 (202)	51.6 (96)	41.9 (106)	0.01	1	.918
Nicotine content of the used e-cigarette[b]				4.39	2	.111
With nicotine	43.1 (87)	47.9 (46)	38.7 (41)			
Without nicotine	29.2 (59)	31.2 (30)	27.4 (29)			
Both	27.7 (56)	20.8 (20)	34.0 (36)			
Electronic media	31.0 (136)	30.6 (57)	31.2 (79)	1.55	1	.213
NRT	26.2 (115)	34.4 (64)	20.2 (51)	3.85	1	**.050**[c]
Kind of NRT used[b]				0.90	2	.638
Only nicotine patches	31.3 (36)	31.2 (20)	31.4 (16)			
Only nicotine gum	23.5 (27)	18.8 (12)	29.4 (15)			
Combination of two or more	27.0 (31)	26.6 (17)	27.5 (14)			
Medical advice	15.5 (68)	17.2 (32)	14.2 (36)	0.00	1	1.0
HNB	14.4 (63)	12.9 (24)	15.4 (39)	1.85	1	.174
Hypnoses	4.1 (18)	4.8 (9)	3.6 (9)	0.00	1	.984
Medication[d]	3.4 (15)	4.8 (9)	2.4 (6)	0.58	1	.447
Acupuncture	3.4 (15)	2.7 (5)	4.0 (10)	0.66	1	.418
Re-use of self-help brochure		-	41.1 (104)	-		
Re-use of quitline		15.6 (29)	-	-		

Note. NRT = nicotine replacement therapy; HNB = heat-not-burn product.
[a] Among participants, who reported at least one quit attempt during the last 9 months at t_2 (*n* = 439). [b] Among participants who reported having an e-cigarette (*n* = 202), NRT (*n* = 115), or HNB (*n* = 63), respectively. [c] Exact value < .05. [d] Varenicline, Bupropion or Cytisine.
Bold: *p*-value < .05.

Table 2. *Sample characteristics at baseline*

Baseline characteristic	**Full sample (*n* = 905)**	**Intervention group (*n* = 477)**	**Control group (*n* = 428)**
Age [a], *M* (*SD*), years	42.8 (12.7)	42.5 (12.8)	43.3 (12.6)
Gender [a], *n* (%)			
Female	442 (48.8)	235 (49.3)	207 (48.4)
Male	462 (51.0)	241 (50.5)	221 (51.6)
Non-binary	1 (0.1)	1 (0.2)	-
German nationality [b], *n* (%)	873 (96.5)	459 (96.2)	414 (96.7)
Education [a, c], *n* (%)			
Low	163 (18.0)	88 (18.4)	75 (17.5)
Middle	261 (28.8)	137 (28.7)	124 (29.0)
High	481 (53.1)	252 (52.8)	229 (53.5)
Employment status, *n* (%)			
Unemployed	171 (18.9)	99 (20.8)	72 (16.8)
Casual	30 (3.3)	16 (3.4)	14 (3.3)
Part time	178 (19.7)	83 (17.4)	95 (22.2)
Full time	526 (58.1)	279 (58.5)	247 (57.7)

Note. [a] Used as a stratification variable.

[b] Reflects the quantity and proportion of participants responding affirmatively.

[c] Assessed with the Fagerström Test for Cigarette Depencence (FTCD).

Table 2 (continued)

Baseline characteristic	Full sample (*n* = 905)	Intervention group (*n* = 477)	Control group (*n* = 428)
Marital status, *n* (%)			
Single	373 (41.2)	212 (44.4)	161 (37.6)
Married/registered civil partnership	389 (43.0)	188 (39.4)	201 (47.0)
Divorced	132 (14.6)	72 (15.1)	60 (14.0)
Widowed	11 (1.2)	5 (1.0)	6 (1.4)
Living with a smoking partner [b], *n* (%)	283 (31.3)	144 (30.2)	139 (32.5)
Living with other smokers in a household [b], *n* (%)	103 (11.4)	55 (11.5)	48 (11.2)
Years of smoking, *M* (*SD*)	23.4 (12.9)	23.6 (13.3)	23.2 (12.5)
Cigarettes smoked per day [a], *M* (*SD*)	16.2 (7.7)	16.3 (8.1)	16.1 (7.4)
Nicotine dependence [c], *M* (*SD*)	3.9 (2.0)	4.0 (2.1)	3.8 (1.9)
Number of past quit attempts, *n* (%)			
None	95 (10.5)	48 (10.1)	47 (11.0)
One	93 (10.3)	41 (8.6)	52 (12.1)
Two	211 (23.3)	105 (22.0)	106 (24.8)
Three	175 (19.3)	95 (19.9)	80 (18.7)
Four	82 (9.1)	48 (10.1)	34 (7.9)
Five or more	249 (27.5)	140 (29.4)	109 (25.5)

Note. [a] Used as a stratification variable.

[b] Reflects the quantity and proportion of participants responding affirmatively.

[c] Assessed with the Fagerström Test for Cigarette Depencence (FTCD).

Table 2 (continued)

Baseline characteristic	Full sample (n = 905)	Intervention group (n = 477)	Control group (n = 428)
Last quit attempt [d], *n* (%)			
Last week	22 (2.7)	9 (2.1)	13 (3.4)
2 - 3 weeks ago	53 (6.5)	25 (5.8)	28 (7.3)
More than 4 weeks ago	126 (15.6)	74 (17.2)	52 (13.6)
More than half a year ago	180 (22.2)	99 (23.1)	81 (21.3)
More than a year ago	429 (53.0)	222 (51.7)	207 (54.3)
Use of smoking cessation aids in attempt to quit/stay quit [b, d], *n* (%)	389 (48.0)	213 (49.7)	176 (46.2)
Importance to quit [e], *M* (*SD*)	86.6 (19.8)	86.5 (20.5)	86.8 (18.9)
Confidence to quit [e], *M* (*SD*)	60.8 (23.7)	60.3 (23.4)	61.3 (24.0)
Suffering from chronic respiratory illness [b], *n* (%)	145 (16.0)	75 (15.7)	70 (16.4)

Note. [b] Reflects the quantity and proportion of participants responding affirmatively.

[d] Only participants with a past quit attempt answered the question ($n_{FullSample}$ = 810, $n_{ProactiveTelephoneCounselling}$ = 429, $n_{Self\text{-}helpBrochure}$ = 381).

[e] Assessed on a Visual Analogue Scale with values ranging from 0 (not at all important/confident) to 100 (very important/confident).

Table 3. *Abstinence outcomes at 12-month assessment*

Abstinence at t_2	**Telephone counselling**	**Self-help brochure**	***OR* [95% CI]**	
ITT sample [a] (*n* = 905)	(*n* = 477) [b]	(*n* = 428) [c]		
Prolonged cigarette abstinence, %	31.7	17.8	2.2	[1.6, 3.0]
Prolonged tobacco abstinence, %	30.8	15.2	2.5	[1.8, 3.5]
7-day cigarette PPA, %	35.8	30.1	1.3	[1.0, 1.7]
7-day tobacco PPA, %	34.8	28.5	1.3	[1.0 [d], 1.8]
CC sample (*n* = 613)	(*n* = 288)	(*n* = 325)		
Prolonged cigarette abstinence, %	52.4	23.4	3.6	[2.6, 5.2]
Prolonged tobacco abstinence, %	51.0	20.0	4.2	[2.9, 6.0]
7-day cigarette PPA, %	57.3	37.2	2.3	[1.6, 3.1]
7-day tobacco PPA, *%*	55.6	35.1	2.3	[1.7, 3.2]

Note. *OR* = odds ratio; CI = confidence interval; ITT = intention-to-treat; PPA = point prevalence abstinence; CC = complete case.
[a] Individuals with unknown smoking status (USS) were classified as non-abstainers. [b] n_{USS} = 167. [c] n_{USS} = 73. [d] Exact *p*-value > 1.

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