# Development and evaluation of a hybrid online training for panic disorder and agoraphobia

**Entwicklung und Evaluation eines hybriden**

**Online-Trainings bei Panikstörung und Agoraphobie**

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# Inhaltsverzeichnis

# Abstract

Panic disorder is a common anxiety disorder, which is associated with high subjective burden as well as a high cost for the health economy. According to the National Treatment Guideline S3, cognitive behavior therapy is recommended as the most effective psychological treatment. However, many people in need do not have access to cognitive behavior therapy. Internet-based interventions have proven to be an effective way to provide access to evidence-based treatment to those affected, thereby reducing gaps in care. For anxiety disorders, such as panic disorder and agoraphobia, a good effectiveness of internet-based interventions has been proven in numerous international studies. However, the internet has changed over the last few years: mobile technologies have considerable potential to further improve the adherence and effectiveness of internet-based interventions.

Against this background, we developed the hybrid online training "GET.ON Panic". In this training, an app has been integrated into a browser-based online training. The app consists of a mobile diary for self-monitoring as well as a mobile exposure-guide that supports participants in self-exposure exercises in their everyday lives.

In an initial exploratory feasibility study, qualitative interview data and quantitative measurements were collected in a pre-post design of 10 participants. Usage, user friendliness, user satisfaction and acceptance of the app were generally considered high. The use of interoceptive exposure exercises and daily summaries of anxiety and mood were the most widely performed and rated the best, while in vivo exposure exercises and the monitoring of acute panic symptoms were found to be difficult.

In the efficacy study, 92 participants with mild to moderate panic symptoms (PAS mean: 9-28) were randomized into two parallel groups. After eight weeks, the intervention group showed a significant improvement in the severity of panic symptoms compared to the waiting control group. Using the intention-to-treat approach, a covariance analysis with baseline values as a covariate yielded a mean effect of Cohen's d=0.66 in reducing the panic symptoms in favor of the intervention group. This effect increased to d=0.89 after three months and stayed at d=0.81 at the 6-month measurement point. Response and remission rates were also significantly higher in the intervention group. This positive effect was also shown for secondary outcomes such as depressive symptoms and quality of life. A correlation between app usage and clinical outcomes could not be found.

This work was the first to demonstrate that a hybrid online training based on cognitive behavior therapy is effective in reducing panic symptoms as well as panic disorder. In addition, this work contributes to a deeper understanding of the potential of mobile technologies in the field of e-mental health. Overall, the GET.ON panic app appears to be an acceptable and motivating component of a hybrid online training for panic disorder and agoraphobia.

# Zusammenfassung

Panikstörung ist eine verbreitete Angststörung, die mit einer hohen subjektiven Belastung sowie hohen gesundheitsökonomischen Kosten einhergeht. Gemäß der nationalen Behandelleitlinie S3 wird kognitive Verhaltenstherapie als wirksamste psychologische Behandlung empfohlen. Viele Betroffene haben jedoch keinen Zugang zur kognitiven Verhaltenstherapie. Internetbasierte Interventionen haben sich als eine wirksame Möglichkeit herausgestellt, Betroffenen Zugang zu evidenzbasierten Behandlungsmethoden zu verschaffen und so Versorgungslücken zu verkleinern. Für Angsterkrankungen, wie Panikstörung und Agoraphobie, konnte in zahlreichen internationalen Studien eine gute Wirksamkeit von internetbasierten Interventionen nachgewiesen werden. Das Internet hat sich jedoch im Laufe der letzten Jahre gewandelt: Mobile Technologien bergen erhebliches Potenzial in sich, die Adhärenz und Wirksamkeit internetbasierter Interventionen weiter zu verbessern.

Vor diesem Hintergrund haben wir das hybride Online-Training „GET.ON Panik" entwickelt. In diesem Training wurde eine App in ein browserbasiertes Online-Training integriert. Die App besteht aus einem mobilem Tagebuch zum Selbstmonitoring sowie einem mobilen Expositionsbegleiter, der Betroffene bei Selbstexpositionsübungen in ihrem Alltag unterstützt.

In einer ersten explorativen Machbarkeitsstudie wurde in einem Prä-Post-Design von 10 Personen qualitative Interviewdaten sowie quantitative Messungen erhoben. Die Nutzung, sowie die Benutzerfreundlichkeit, Nutzerzufriedenheit und Akzeptanz der App wurden allgemein als hoch empfunden. Interozeptive Expositionsübungen und tägliche Zusammenfassungen zum Angsterleben und zur Stimmung wurden am häufigsten durchgeführt und am besten bewertet, während in-vivo Expositionsübungen und das Monitorieren von akuten Paniksymptomen hingegen als schwierig empfunden wurden.

In der auf die Machbarkeitsstudie folgenden Wirksamkeitsstudie wurden 92 Personen mit mild bis moderat ausgeprägten Panikbeschwerden (PAS Mittelwert: 9-28) in zwei parallele Gruppen randomisiert. Nach acht Wochen zeigte die Interventionsgruppe eine signifikante Verbesserung der Schwere der Paniksymptome im Vergleich zur Warte-Kontrollgruppe. Die Kovarianzanalyse mit den Baseline-Werten als Kovariate, ergab nach dem Intention-to-treat Ansatz einen mittleren Effekt von Cohen's d=0,66 in der Reduzierung der

Panikbeschwerden zu Gunsten der Interventionsgruppe. Dieser Effekt stieg nach drei Monaten auf d=0,89 an und hielt sich zum 6-Monats Messzeitpunkt bei d=0,81. Auch Response- wie Remissionsraten waren bei der Interventionsgruppe signifikant höher. Dieser positive Effekt zeigte sich ebenfalls für sekundäre Endpunkte wie depressive Beschwerden und Lebensqualität. Ein Zusammenhang zwischen App-Nutzung und klinischen Zielkriterien konnte nicht gefunden werden.

Mit dieser Arbeit konnte erstmals gezeigt werden, dass ein auf kognitiver Verhaltenstherapie beruhendes hybrides Online-Training zur Reduktion von Panikbeschwerden und Panikstörung wirksam ist. Zudem trägt diese Arbeit zu einem tieferen Verständnis des Potenzials mobiler Technologien im Feld E-Mental Health bei. Insgesamt scheint die GET.ON Panik App ein akzeptabler und motivierender Bestandteil eines hybriden Online-Trainings für Panikstörung und Agoraphobie zu sein.

# Kapitel 1: Allgemeine Einleitung

In dieser Arbeit wird die Entwicklung, Machbarkeit und Wirksamkeit eines Online-Trainings für Menschen, die unter Symptomen von Panikstörung und Agoraphobie leiden, vorgestellt. Das Online-Training trägt den Namen „GET.ON Panik" und basiert auf den Prinzipien der kognitiven Verhaltenstherapie. Es besteht aus einem browserbasierten Trainingspart und einer mobilen App, für das von nun an die Bezeichnung „hybrides" Online-Training angeführt wird.

Dieses einleitende Kapitel befasst sich mit der Prävalenz und Behandlung von Panikstörungen, skizziert den *State-of-the-art* der onlinebasierten Behandlungsmöglichkeiten und berücksichtigt neueste Entwicklungen im Feld der *M-Health Apps*. Es endet mit einer Darstellung der Ziele der vorliegenden Forschungsarbeit sowie einem Überblick der in dem Dissertationsvorhaben durchgeführten Studien, welche in den verbleibenden Kapiteln dieser Arbeit beschrieben werden.

## Panikstörung und Agoraphobie

Angst ist eine natürliche Reaktion des Menschen. Sie hilft, reale Gefahren zu vermeiden und dient in ihrem ursprünglichen Sinne dem Schutze des Überlebens. Bei Personen mit Angststörungen werden die Angstreaktionen jedoch als nicht mehr angemessen beurteilt.

Die Panikstörung ist eine häufig vorkommende Angststörung (Baxter, Vos, Scott, Ferrari, & Whiteford, 2014). Die großangelegte *National Comorbidity Survey Replication* Befragung (Kessler et al., 2006) zeigt, dass innerhalb eines Jahres 2,8% der US-amerikanischen Bevölkerung an einer Panikstörung ohne Agoraphobie und 0,4% an einer Panikstörung mit Agoraphobie leiden. Die Lebenszeitprävalenz wurde für Panikstörung ohne Agoraphobie auf 3,7% und für Panikstörung mit Agoraphobie auf 1,1% der Allgemeinbevölkerung geschätzt (Kessler et al., 2006). Zusätzlich leiden jährlich 11,2% der Befragten unter Panikattacken, ohne dabei die Kriterien einer Panikstörung voll zu erfüllen (Kessler et al., 2006). Symptome einer subklinischer Panikstörung stellen Risikofaktoren für die Entwicklung einer voll diagnostizierbaren Panikstörung dar (Ehlers, 1995; Katerndahl, 1999). Europäische sowie nationale epidemiologische Studien weisen lediglich auf geringfügige Differenzen der Prävalenzraten hin. Einer im Namen des Robert Koch-Instituts durchgeführten Studie zur Gesundheit Erwachsener in Deutschland (DEGS1-MH) zufolge, liegt bei 2% der

Allgemeinbevölkerung eine Panikstörung mit oder ohne Agoraphobie[1] vor (Jacobi et al., 2014). In der EU-weiten Gesamtbevölkerung spiegeln sich diese Prävalenzraten ebenfalls wider (Wittchen & Jacobi, 2005; Wittchen et al., 2011). Frauen sind dabei ungefähr doppelt so häufig betroffen wie Männer. Der Median für das Lebensalter bei Erstauftreten einer Panikstörung liegt bei 24 Jahren (Kessler, Berglund, et al., 2005). Die Diagnose Panikstörung wird aufgrund des somatisch geprägten Erscheinungsbildes jedoch oft erst spät gestellt. Dies wirkt sich ungünstig auf den weiteren Verlauf der Erkrankung (Benatti et al., 2016; Löwe et al., 2003; Wang et al., 2005) und die Entwicklung von Komorbiditäten aus – andere Angststörungen, affektive Störungen oder Suchterkrankungen sind häufige Folgeprobleme (Kessler et al., 2006; Kessler, Tat Chiu, et al., 2005).

Die Erkrankung geht mit einer hohen Krankheitslast einher. Betroffene fühlen sich stark eingeschränkt und nehmen besonders viele Leistungen des Gesundheitssystems in Anspruch (Smit et al., 2006). Pro 10.000 Einwohner der 27 befragten EU-Länder werden 9,2 Lebensjahre mit Beeinträchtigung aufgrund von Krankheit (*Disability-Adjusted Life Year* [DALY]) bemessen (Wittchen et al., 2011). Die Erkrankung verursacht einen volkswirtschaftlichen Schaden von jährlichen Pro-Kopf-Kosten in Höhe von 10.269€. Hinzu kommen die Kosten für subklinische Panikstörung, die auf 6.384€ geschätzt werden (Batelaan, De Graaf, Van Balkom, Vollebergh, & Beekman, 2007).

Zur Erklärung der Ätiologie von Panikstörungen wurden in den letzten Jahrzehnten verschiedene Modelle basierend auf z. B. biologischen, psychodynamischen oder lerntheoretischen Annahmen, entwickelt (für eine Übersicht vgl. Barlow, 2002). Gegenwärtig werden in Wissenschaft und psychotherapeutischer Praxis vorzugsweise multifaktorielle Entwicklungsmodelle (Barlow, 2002; Clark, 1986; Margraf & Ehlers, 1989) herangezogen. Nach dem psychophysiologischen Modell von Margraf und Ehlers entstehen Panikattacken durch verschiedene Rückkopplungsprozesse zwischen körperlichen Symptomen, derer Assoziation mit Gefahr und der daraus resultierenden Angstreaktion (Margraf & Ehlers, 1989, 1990). Initial führt ein externer oder interner Stimulus zu einer erregungsbedingten somatischen oder kognitiven Veränderung (z. B. Herzklopfen oder Schwindel), die wahrgenommen und als Gefahr fehlinterpretiert wird. Dadurch entsteht ein Gefühl von

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[1] Agoraphobie wurde im DSM-5 als eigenständige Diagnose eingeführt und kann komorbid zur Panikstörung diagnostiziert werden, während Panikstörung und Agoraphobie im DSM-IV noch als eine gemeinsame Störung aufgefasst wurden (Ehret & Berking, 2013).

Angst beziehungsweise Panik. Der „Teufelskreis der Angst" setzt sich in Gang. Die Angst verstärkt die Intensität der physiologischen Reaktionen, die weiter als interne Gefahrensignale wahrgenommen und als zunehmend bedrohlich interpretiert werden, bis sie in eine Panikattacke mündet.

**Leitliniengerechte Therapie bei Panikstörung und Agoraphobie**

Die S3-Leitlinie zur Behandlung von Angsterkrankungen (Bandelow, Lichte, Rudolf, Wiltink, & Beutel, 2015) sieht Psychotherapie und Pharmakotherapie mit Antidepressiva zur Behandlung von Panikstörung gleichermaßen vor. Die Schwere der Erkrankung, die Präferenz des Patienten, Wirkeintritt, Nachhaltigkeit, Nebenwirkungen und Verfügbarkeit sollen laut Leitlinie als Entscheidungskriterien für die Wahl der Therapieform herangezogen werden. Die kognitive Verhaltenstherapie wird mit dem höchsten Evidenz- und Empfehlungsgrad als das Mittel der Wahl aller psychotherapeutischen Verfahren eingestuft. Es geht dabei darum, dass der Betroffene die Erfahrung macht, dass die situativ induzierte Angst unbegründet und ungefährlich ist. Dies gelingt am besten mit therapeutenbegleiteter Exposition, in der Habituation der Angstreaktion erlebt werden muss und die zentrale Befürchtung widerlegt wird (Gloster et al., 2011). Bei der Panikstörung ist insbesondere die Konfrontation mit interozeptiven Reizen relevant, bei der Agoraphobie insbesondere die Konfrontation mit situativen Reizen.

Während die Evidenzlage zur nichttherapeutengestützten kognitiven Verhaltenstherapie, angeboten durch Bücher, Audiomaterial, Computer oder Internet im Sinne einer Anleitung zur Selbsthilfe, in Deutschland noch sehr kontrovers diskutiert wird und lediglich als erste Empfehlungen zur Überbrückung bis zum Therapiebeginn oder als therapiebegleitende Maßnahme als Expertenkonsens in die S3-Leitlinie mit aufgenommen wurde, sind Selbsthilfe-Interventionen in Ländern, wie Großbritannien (National Institute for Health and Care Excellence [NICE], 2011) und den Niederlanden (van Balkom et al., 2013) bereits als fester Bestandteil in den Behandlungsleitlinien im Sinne einer gestuften Versorgung (*stepped-care*) aufgenommen.

**Schwierigkeiten im Zugang zu leitliniengerechter Therapie**

Für viele betroffene Personen mit Panikstörung ist der Zugang zu einer leitliniengemäßen Therapie erschwert. Die Gründe dafür sind divers. So besagt die DEGS1-MH Studie, dass aus der Gruppe der Personen, die an einer Panikstörung leiden, sich im Laufe von einem Jahr nur 41,8% in irgendeiner Form in Behandlung wegen dieser Störung befinden (Jacobi

et al., 2014; Mack et al., 2014). Im Vergleich zu anderen psychischen Erkrankungen ist diese Zahl sogar verhältnismäßig hoch. Viele Personen mit Panikstörung neigen durchaus dazu Hilfe zu suchen, erhalten diese jedoch oft unzureichend. Obwohl der Einsatz von kognitiver Verhaltenstherapie konform aktueller Leitlinien empfohlen wird (Bandelow et al., 2015; NICE, 2011; van Balkom et al., 2013), werden nur ein Fünftel aller Personen, die Kontakt zu ÄrztInnen und TherapeutInnen aufgenommen haben, mit kognitiver Verhaltenstherapie behandelt (Andrews, Issakidis, & Carter, 2001). Als einer der möglichen Gründe kann genannt werden, dass die Erkrankung zunächst nicht erkannt und die Symptome somatischen Ursachen zugeschrieben werden (Greenslade, Hawkins, Parsonage, & Cullen, 2017; Locke, Kirst, & Shultz, 2015; Mack et al., 2014). Zusätzlich erschweren Barrieren, wie mangelnde Gesundheitskompetenz, geringfügige Kenntnisse über Angebote des Gesundheitssystems, Angst vor Stigmatisierung sowie infrastrukturelle Faktoren das Aufsuchen von Hilfe seitens der Betroffenen (Coles & Coleman, 2010; Mojtabai et al., 2011). Erschwerend kommt hinzu, dass Personen, die sich für eine kognitive Verhaltenstherapie entschieden haben, oft erst nach einigen Monaten Wartezeit einen Therapieplatz finden (Zepf, 2001). Insgesamt besteht in Deutschland eine unzureichende Versorgung durch leitliniengemäße Therapie an Panikstörung erkrankter Menschen.

## E-Mental Health

In den letzten Jahren ist durch *E-Mental Health* eine neue Form der psychologischen und psychiatrischen Versorgung entstanden. E-Mental Health wird generisch als „Nutzung von Informations- und Kommunikationstechnologien zur Unterstützung und Verbesserung des psychischen Befindens und der seelischen Versorgung" definiert (Riper et al., 2007). Die Angebote reichen von einfachen informativen Webseiten und Foren, über von Patienten, Krankenkassen oder Pharmafirmen entwickelte Gesundheits-Apps bis hin zu wissenschaftlich evaluierten internetbasierten Interventionen[2] (Klein et al., 2016). In Hinblick auf die oben skizzierten Schwierigkeiten im Zugang zu leitliniengerechter Therapie stellen internetbasierte Interventionen eine Möglichkeit dar, Versorgungslücken bei psychischen Beschwerden zu verkleinern.

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[2] Internetbasierte Interventionen werden in der Literatur häufig auch als webbasierte Interventionen, onlinebasierte Interventionen oder Online-Trainings bezeichnet.

Internetbasierte Interventionen verfolgen vor allem das Ziel, den psychischen Zustand der betroffenen Person zu verbessern. Sie umfassen strukturierte Übungen, in denen Techniken im Umgang mit dem Beschwerdebild vermitteln werden. Die Interventionen werden dem Betroffenen typischerweise auf einer Webseite, per E-Mail oder über eine mobile Applikation für Tablet Computer oder Smartphone bereitgestellt. Charakteristische Unterschiede zwischen verschiedenen Interventionen können in den zugrundeliegenden theoretischen Ansätzen, der Darreichungsform, der Trainingslänge, dem Maß an Interaktivität und der Intensität der Unterstützung bestehen. Für Interventionen, die auf kognitiver Verhaltenstherapie basieren, eine mittlere Länge (5-10 Trainingseinheiten) aufweisen und in begleiteter Selbsthilfe angeboten werden, liegt derzeit die meiste Evidenz vor (Andersson, Carlbring, Berger, Almlöv, & Cuijpers, 2009; Richards & Richardson, 2012; Spek et al., 2007).

Als Stärken internetbasierter Interventionen gelten vor allem eine verbesserte Erreichbarkeit, der flexible Einsatz, geringe Kosten, eine hohe Skalierbarkeit für eine breite Masse, sowie eine anonyme Nutzbarkeit (Andersson, 2010; Andersson & Titov, 2014; Andersson, Titov, Dear, Rozental, & Carlbring, 2019). Folgende Nachteile bzw. Risiken und Barrieren werden im Zusammenhang mit E-Mental Health thematisiert: Sie erfordern hohe Selbstmanagementfähigkeiten von den Teilnehmenden (Melville, Casey, & Kavanagh, 2010) und stellen strenge Anforderungen an den Datenschutz (Bennett, Bennett, & Griffiths, 2010; Klein et al., 2016). Zudem taucht in der aktuellen Diskussion immer wieder die Frage auf, in wie weit ein internetbasiertes Hilfsangebot auf akute Krisen und Suizidalität angemessen reagieren kann, was insbesondere bei einer anonymen Nutzung des Angebots hochrelevant ist (Bundespsychotherapeutenkammer, 2017).

**Evidenz von E-Mental Health**

Nach heutigem Stand belegen über 300 internationale Studien die Wirksamkeit von internetbasierten Interventionen für ein breites Spektrum an Störungsbildern, wie Depressionen (Karyotaki et al., 2017; Richards & Richardson, 2012), Angststörungen (Adelman, Panza, Bartley, Bontempo, & Bloch, 2014; Lewis, Roberts, Bethell, Robertson, & Bisson, 2018; Mayo-Wilson & Montgomery, 2013), Essstörungen (Beintner, Jacobi, & Taylor, 2012) oder Suchterkrankungen (Riper et al., 2018). Neben Studien zu psychiatrischen Erkrankungen gibt es eine umfangreiche Literatur zu verschiedenen Gesundheitsproblemen, wie chronischen Schmerzen (Martorella et al., 2017), berufsbedingtem Stress (Heber et al.,

2017) oder Tinnitus (Andersson, 2015), um nur einige Beispiele zu nennen. Erste Studien deuten darauf hin, dass internetbasierte Interventionen, die in Begleitung eines Coaches angeboten werden, genauso effektiv sein können wie *face-to-face* Psychotherapie (Andersson, Cuijpers, Carlbring, Riper, & Hedman, 2014; Andrews et al., 2018; Carlbring, Andersson, Cuijpers, Riper, & Hedman-Lagerlöf, 2018) Ebenfalls liegt hinsichtlich der Kosteneffektivität internetbasierter Interventionen stetig mehr Evidenz vor (u. a. Buntrock et al., 2017; Hedman, Ljótsson, & Lindefors, 2012; Nobis et al., 2018; Thiart et al., 2016).

Das zuvor skizzierte Bild der wachsenden (metaanalytischen) Evidenz für E-Mental Health zeichnet sich ebenfalls für Panikstörungen und Agoraphobie ab (Andrews et al., 2018; Andrews, Cuijpers, Craske, McEvoy, & Titov, 2010; Haug, Nordgreen, Öst, & Havik, 2012; Spek et al., 2007). Als ein Beispiel ist das *Cochrane-Review* von Mayo-Wilson und Montgomery zu nennen, in dem 21 Studien zu *media-delivered* Selbsthilfe-Trainings mit insgesamt 797 Teilnehmende aufgenommen und ausgewertet wurden (2013). Die standardisierte Mittelwertdifferenz (SMD) liegt bei 0.62 (95% KI 0,45-0,79) zugunsten der internetbasierte Interventionen über Kontrollbedingungen, wie Wartelisten, Aufmerksamkeit, psychoedukative Informationen oder Online-Diskussionsgruppen (Mayo-Wilson & Montgomery, 2013). Zudem verdichten sich auch hier die Beweise dafür, dass internetbasierte Interventionen und face-to-face Behandlungen gleich wirksam sein können (Andersson, 2012; Andersson, Cuijpers, Carlbring, Riper, & Hedman, 2014; Andrews et al., 2018; Cuijpers, Donker, van Straten, Li, & Andersson, 2010; Olthuis, Watt, Bailey, Hayden, & Stewart, 2015).

Auch wenn die Studienlage vielversprechend ist, bergen internetbasierte Methoden im Vergleich zu herkömmlichen face-to-face Therapien Risiken, die die Gesundheit und den Behandlungserfolg der Teilnehmenden gefährden können (Bundespsychotherapeutenkammer, 2017). Das Fehlen an direkter therapeutischer Unterstützung während des Online-Trainings, ist als ein Beispiel zu nennen. Der Mangel an direkter Unterstützung kann das Risiko erhöhen, dass KlientInnen die Behandlung nicht vollständig ausführen oder gar komplett abbrechen (Boschen & Casey, 2008). Insbesondere Selbstexpositionsübungen stellen für Teilnehmende von Online-Trainings für Panikstörung eine große Herausforderung dar. Studienteilnehmende, die Selbstexpositionen durchgeführt haben, brachen das Online-Training vergleichsweise häufiger ab (Marks, Kenwright, McDonough, Whittaker, & Mataix-Cols, 2004; van Ballegooijen et al., 2013). Vor diesem

Hintergrund stellen sich die Fragen, wie Teilnehmende bei der bei Selbstexpositionen besser unterstützt werden können und wie ein alltagsnahes Trainieren für sie erleichtert werden kann.

**M-Mental Health**

Mit über 5 Milliarden weltweiten Nutzern zählt das Smartphone zu den größten technologischen Innovationen der letzten Jahre. Die jährliche Wachstumsrate mobiler Internetzugänge ist mit über 20% mehr als doppelt so hoch wie die stationärer[3] Internetzugänge (International Technology Union, 2017). *M-Mental Health* verspricht aufgrund ständiger Verfügbarkeit und spezifischer Beschaffenheit mobiler Endgeräte den Zugang zu einer evidenzbasierten Gesundheitsversorgung zu erleichtern (Mohr, Burns, Schueller, Clarke, & Klinkman, 2010; Price et al., 2014; Proudfoot, 2013). M-Mental Health umfasst die Nutzung beziehungsweise das Zunutze machen der Kernfunktionen eines Mobiltelefons, wie den Sprach- und Kurzmitteilungsdienst (SMS), komplexere Funktionen und Anwendungen, einschließlich Allgemeiner Paketorientierter Funkdienst (GPRS), Mobilfunk der dritten und vierten Generation (3G- und 4G-Systeme), Globales Positionsbestimmungssystem (GPS) und Bluetooth-Technologie, im Rahmen psychologischer oder psychiatrischer Interventionen (World Health Organization, 2011). M-Mental Health-Apps können entweder als eigenständige Selbsthilfeprogramme (*stand-alone*) oder als zusätzliche Behandlungstools (*add-on*) in strukturierte Programmen integriert werden, zum Beispiel als Teil eines browserbasierten Trainings – hybrides Format –, oder auch ihren Einsatz im Rahmen einer face-to-face Behandlung finden – dies wird als *blended* Format bezeichnet. Sinnvolle Einsatzgebiete von mobiler Technologie können zum einen *ecological momentary assessments* – Datenerhebungen, bei denen wiederholt und alltagsnah Daten zu psychologischen Parametern, beispielsweise Schlaf, Stimmung oder Angsterleben, gesammelt werden (Alpers, 2009; Helbig, Lang, Swendsen, Hoyer, & Wittchen, 2009; Moskowitz, Russell, Sadikaj, & Sutton, 2009; Myin-Germeys et al., 2009; Trull & Ebner-Priemer, 2009), und zum anderen *ecological momentary interventions* sein – kleinere therapeutische Übungen, die in der realen Welt und in Echtzeit durchgeführt werden (Heron & Smyth, 2010).

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[3] Internetzugang über PC oder Laptop-Computer

In Bezug auf Panikstörung könnte sich der Einsatz von Smartphones positiv auf die Trainingsadhärenz und die Wirksamkeit von internetbasierten Interventionen auswirken. So könnten mobile Komponenten die Teilnehmenden bei in-vivo Expositionsübungen in ihrer natürlichen Umgebung unterstützen. Darüber hinaus könnte ein mobiles Tagebuch zu einem besseren Echtzeit-Monitoring der Symptome beitragen und so eine Verzerrung der Einträge durch retrospektiven *Recall-Bias* potenziell verhindern (Ebner-Priemer et al., 2006; Ebner-Priemer & Trull, 2009; Stone & Broderick, 2007).

**Evidenz M-Mental Health**

In den gängigen App-Stores sind massenhaft Angebote an gesundheitsfördernden Apps zum ständigen Download verfügbar. Die wenigsten kommerziell erhältlichen Apps wurden jedoch einer wissenschaftlichen Evaluation unterzogen (Bakker, Kazantzis, Rickwood, & Rickard, 2016; Donker et al., 2013; Wisniewski et al., 2019; [Depressions-Apps: Shen et al., 2015, Soziale Phobie-Apps: Alyami, Giri, Alyami, & Sundram, 2017, Angst-Apps: Sucala et al., 2017]). Angesichts des rasanten Wachstums und des Potenzials mobiler Technologien, wurde wenig dazu geforscht, wie Smartphones als stand-alone oder add-on Intervention im Rahmen eines hybriden Online-Trainings eingesetzt werden können. Die ersten Wirksamkeitsstudien sind jedoch vielversprechend (Ebert et al., 2018; Ehrenreich, Righter, Rocke, Dixon, & Himelhoch, 2011), insbesondere was den Einsatz mobiler Technologien zur Reduktion von Depression (Ly, Trüschel, et al., 2014; Ly et al., 2015), Angst (Christoforou, Sáez Fonseca, & Tsakanikos, 2017; Domhardt, Geßlein, von Rezori, & Baumeister, 2018; Firth et al., 2017; Ivanova et al., 2016; Proudfoot et al., 2013) sowie weiterer Gesundheitsprobleme (Carter, Burley, Nykjaer, & Cade, 2013; Fanning, Mullen, & McAuley, 2012; Ly, Asplund, & Andersson, 2014; Whittaker, McRobbie, Bullen, Rodgers, & Gu, 2016) betrifft. In einer ersten Metaanalyse für den Bereich Angststörungen konnte aufgezeigt werden, dass sich allgemeine Angstzustände durch mobile transdiagnostische E-Health Interventionen deutlich reduzieren ließen (Hedge's g=0,45) (Firth et al., 2017). Nichtsdestotrotz ist die Forschungslage noch unzureichend.

In Hinblick auf die Benutzerfreundlichkeit gilt es zu berücksichtigen, dass mobile Anwendungen auch einige Nachteile aufweisen. Beispielsweise sind umfangreiche Schreibaufgaben, wie sie typischerweise in der kognitiven Verhaltenstherapie Anwendung finden, mit Hilfe eines kleinen Smartphone-Touchpad schwer zu erledigen. Hybride Interventionen, die die Vorteile der Desktop- und der Smartphonetechnologie miteinander

kombinieren, haben großes Potenzial den ausschließlich desktop- oder mobilbasierten Ansätzen hinsichtlich Adhärenz und Wirksamkeit überlegen zu sein (Christoforou et al., 2017; Ivanova et al., 2016; Proudfoot et al., 2013).

## Zusammenfassung und aktuelle Herausforderungen

Vor dem Hintergrund des skizzierten Forschungsstandes lässt sich festhalten, dass die Digitalisierung unwiderruflich Einzug in die psychologische Versorgung gehalten hat. Innovative Technologien, wie internetbasierte Interventionen und Smartphone-Apps, bieten das Potenzial Versorgungslücken zwischen evidenzbasierten Hilfsangeboten und den betroffenen Personen, die aufgrund von persönlichen Präferenzen oder strukturellen Barrieren keinen Zugang zu adäquaten Versorgungsangeboten haben, zu verringern. Allerdings fehlt es an evaluierten Interventionen für die Vielzahl an Personen, die unter Symptomen von Panikstörung und Agoraphobie leiden, die erstens den Goldstandard der psychologischen Interventionen, nämlich Expositionen, integrieren, zweitens eine Kombination von desktopbasierter und mobiler Trainingselemente nutzen, und drittens innovative Technologien so einsetzen, dass ein flexibles, alltagsnahes und störungsgerechtes Trainieren möglich ist. Neben fehlenden Wirksamkeitsstudien sind zusätzlich initiale, explorative Machbarkeitsstudien erforderlich, die erlauben, Rückschlüsse über die Bedienbarkeit, Machbarkeit und Technologieakzeptanz innovativer Instrumente bei der Behandlung psychischer Beschwerden zu ziehen, um so die weitere technologische Entwicklung zu optimieren.

## Ziele der vorliegenden Arbeit

Das Hauptziel der vorliegenden Arbeit war es, ein hybrides Online-Training bestehend aus einer desktopbasierten Intervention und einer integrativen Smartphone-App für Personen, die unter Symptomen von Panikstörung und Agoraphobie leiden, zu entwickeln und dieses hinsichtlich seiner Machbarkeit und Wirksamkeit zu evaluieren. Im Einzelnen verfolgte die vorliegende Arbeit dabei folgende Teilziele:

## (I) Entwicklung eines hybriden Online-Trainings bei Panik- und Agoraphobiesymptomen

Das erste Ziel war es, ein hybrides Online-Training zu entwickeln, welches aus zwei Komponenten besteht: Erstens, einer mobilen Komponente, welche zwei Funktionen

erfüllt, nämlich die Bereitstellung eines mobilen Tagebuches zum Monitorieren der Angstsymptome sowie die Anleitung einer appgeführten Selbstexposition; zweitens, einer Desktop-Komponente, die text- und videobasierte Psychoedukation sowie ausführliche Schreibaufgaben auf einer browserbasierten Trainingsplattform anbietet. Zur Evaluation der Wirksamkeit dieses hybriden Online-Trainings wurde das Design für eine randomisierte kontrollierte Studie mit einem Vergleich zwischen Interventionsgruppe und Wartelisten-Kontrollgruppe zu einem 8-Wochen-, 3-Monats- und 6-Monats-Follow-Up geplant und vorgestellt.

**(II) Entwicklung und Überprüfung der Machbarkeit einer mobilen Smartphone-App bei Panikstörung und Agoraphobie**

Das zweite Ziel war es, die mobile Smartphone-Applikation, die im Rahmen des hybriden Online-Paniktraining (I) in einer interdisziplinären Zusammenarbeit entwickelt wurde, in einer initialen explorativen Machbarkeitsstudie zu untersuchen und zu verbessern. Zur Überprüfung der Machbarkeit wurden quantitative Daten zur App-Nutzung sowie qualitativer Interviewdaten zur Technologieakzeptanz sowie Nutzung bei 10 Teilnehmenden erhoben.

**(III) Überprüfung der Wirksamkeit des hybriden Online-Training bei Panikstörung und Agoraphobie**

Das dritte Ziel war, die unter (I) geplante randomisierte kontrollierte Studie mit 92 Personen mit leichter bis moderaten Panikbeschwerden (Panik- und Agoraphobie Skala 9–28) durchzuführen und hinsichtlich Wirksamkeit des hybriden Online-Trainings auszuwerten. Die Studienteilnehmenden wurden in zwei Gruppen unterteilt: Eine Gruppe erhielt unmittelbar Zugang zum Training mit begleitendem Online-Coach, die erst nach einer Wartezeit von 6 Monaten. Die primäre Hypothese war, dass sich die Interventionsgruppe signifikant stärker hinsichtlich Panikbeschwerden, aber auch in Bezug auf sekundäre Maße wie depressive Beschwerden, Lebensqualität sowie weitere Angstmessungen (z. B. Schwere der Angststörung durch Fremdbeurteilung, Ansprech- und Remissionsraten) verbessert als die Wartelisten-Kontrollgruppe.

## Darstellung des Dissertationsvorhabens

Im Rahmen der vorliegenden Dissertation wurde ein hybrides Online-Training bestehend aus einem desktopbasierten Training und einer mobilen Smartphone-Applikation für

Personen, die unter Panikbeschwerden leiden, entwickelt, explorativ auf seine Machbarkeit hin untersucht und anschließend hinsichtlich seiner klinischen Wirksamkeit in einer randomisierten kontrollierten Studie evaluiert. Eingebettet in eine allgemeine Einführung (Kapitel 1) und abschließende Diskussion (Kapitel 5) besteht diese Dissertation aus zwei Studien und drei Manuskripten, die entweder bereits in Fachzeitschriften publiziert (Kapitel 3) oder zur Publikation eingereicht wurden (Kapitel 2 und 4).

**Kapitel 2: Entwicklung und Machbarkeitsstudie GET.ON Panik App**

Kapitel 2 widmet sich dem Entwicklungsprozess der GET.ON Panik App und beinhaltet Ergebnisse der initialen Machbarkeitsstudie. Die App-Entwicklung umfasst den Zeitraum von November 2011 bis März 2013, im April und Mai 2013 folgte die Machbarkeitsstudie, woraufhin die App im Juni und Juli 2013 überarbeitet wurde, bevor sie im Rahmen der geplanten randomisierten kontrollierten Studie eingesetzt wurde. Die Machbarkeitsstudie bietet einerseits einen kurzen Überblick über die interdisziplinäre Entwicklungsphase der mobilen Anwendung und andererseits erste Einblicke in die Nutzung, Verwendbarkeit und Akzeptanz der mobilen Anwendung mit quantitativen Maßen sowie mit qualitativen Interview Daten der Teilnehmenden (N=10). Das Manuskript wurde im März 2019 in der Fachzeitschrift *Internet Interventions* eingereicht und befindet sich aktuell unter Begutachtung. Das Manuskript wird als erster Fachartikel der kumulativen Dissertation angeführt.

**Kapitel 3: Studienprotokoll GET.ON Panik**

Das hybride Online-Training GET.ON Panik wurde im Zeitraum von November 2011 bis August 2013 im Rahmen des Forschungsprojektes Gesundheitstrainings.Online des Innovations-Inkubators an der Leuphana Universität Lüneburg entwickelt. Die geplante randomisierte kontrollierte Studie verfolgte das Ziel, die Wirksamkeit der Intervention im Vergleich zu einer Wartelisten Kontrollgruppe zu bewerten. Das Studienprotokoll enthält eine detaillierte Beschreibung der Intervention sowie eine Vorstellung der statistischen Methodik, wie die Beschreibung des Rekrutierungsprozesses, der Messmethoden und Analysetechniken. Das Manuskript wurde im November 2014 in der Zeitschrift *Trials* veröffentlicht und stellt in Kapitel 3 den zweiten Fachartikel dieser kumulativen Dissertation dar.

**Kapitel 4: Wirksamkeitsstudie GET.ON Panik**

Im Anschluss an die Machbarkeitsstudie wurde ab August 2013 eine Wirksamkeitsstudie zum hybriden Online-Training GET.ON Panik durchgeführt. Es wurden 92 Erwachsene mit milden bis moderaten Panikbeschwerden in die Studie eingeschlossen und in einen der beiden Studienarme per Zufall zugewiesen. Die Interventionsgruppe erhielt sofortigen Zugang zum GET.ON Panik Online-Training, welches mit minimaler Begleitung durch einen Online-Coach angeboten wurde. Der Kontrollgruppe wurde das Training nach einer Wartezeit von 6 Monaten zur Verfügung gestellt. Die Ergebnisse dieser randomisierten kontrollierten Studie zum 8-Wochen-, 3-Monats- und 6-Monats- Messzeitpunkt wurden im März 2019 zur Publikation bei der Fachzeitschrift *Journal of Consulting and Clinical Psychology* eingereicht und befinden sich aktuell unter Begutachtung. In Kapitel 4 wird der dritte Fachartikel dieser Dissertation vorgestellt.

**Kapitel 5: Allgemeine Diskussion**

Im letzten Kapitel werden die Ergebnisse aus den vorherigen drei Manuskripten zu einem kohärenten Bild zusammengefügt und abschließend diskutiert. Insbesondere wird darauf eingegangen, welche konkreten klinischen sowie technischen Implikationen, sich aus den Befunden ableiten lassen, um so die psychische Gesundheit von Menschen, die unter Panikbeschwerden leiden, verbessern zu können.

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# Kapitel 2: Entwicklung und Machbarkeitsstudie GET.ON Panik App

## A mobile application for panic disorder and agoraphobia: Insights from a multi-methods feasibility study

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## Abstract

### Background

Panic disorder with and without agoraphobia (PD) is a common psychological disorder. Internet-based interventions have the potential to offer highly scalable low-threshold evidence-based care to people suffering from PD. GET.ON Panic is a newly developed internet-based intervention addressing symptoms of PD. In order to transfer the training into the daily life of the individuals, we integrated mobile components in the training and created a so-called hybrid online training. The development and beta-testing of such a training requires a novel interdisciplinary approach between IT specialists and psychologists. From this point of view, we would like to share our experiences in this exploratory paper.

### Methods

This initial feasibility study (N= 10) offers, on the one hand, a brief overview of the interdisciplinary development phase of the mobile application and on the other hand, provides first insights into the usage, usability and acceptance of this mobile application using qualitative interview data as well quantitative measures of 8 completing participants. For these reasons, we used a pre-posttest design without a control group. Furthermore, we present initial clinical outcomes of the intervention on e.g. panic symptom severity, depressive symptoms as well additional anxiety measures. Finally, we end with implications for further research in the relatively new field of mobile mental health.

### Results

Overall, usability, user satisfaction, motivational value and technology acceptance of the app were perceived as high. The usage of app components was diverse: The use of interoceptive exposure exercises and daily summaries on anxiety and mood was highest while using in-vivo exposure exercises and monitoring panic symptoms was perceived as difficult. Furthermore, participants showed after the training less clinical symptoms as at baseline-assessment.

### Discussion

The current feasibility study contributes to an in-depth understanding of the potential of mobile technology in e-mental health. Overall, the GET.ON Panic app appears to be an acceptable and motivational part of a CBT-based hybrid online training for PD that has the

potential to promote training success. After some suggested adjustments have been made, the efficacy should be investigated in a randomized controlled trial.

**Keywords**

m-mental health; panic disorder; agoraphobia; feasibility study; thematic analyses; cognitive behavior therapy

## Background

Panic disorder with and without agoraphobia (PD) is with a life-time prevalence of 1.1%−3.7% a common anxiety disorder (Jonge et al., 2016; Kessler et al., 2006) that causes serious impairments for the individual (Wittchen et al., 2011) as well high economic costs from a societal perspective (Batelaan et al., 2007; Ophuis et al., 2018). Cognitive-behavioral therapy (CBT) is a widely used effective treatment for PD (Pompoli et al., 2016; Sánchez-Meca et al., 2010), which – in the last decade – has found increasing use in internet-based interventions (iCBT) and has proven to be acceptable and effective for the treatment of PD (Andrews et al., 2018; Andrews et al., 2010; Olthuis et al., 2015) as well other mental disorders such as depression or anxiety disorders in general (Andersson et al., 2014; Carlbring et al., 2006; Lewis et al., 2018; Richards and Richardson, 2012).

Considering an annual increase of 20% of new mobile-broadband subscriptions to a worldwide number of 4 billion people using mobile internet, compared to a 9% growth rate for fixed-broadband subscriptions per year ([ITU]International Technology Union, 2017), smartphones are promising to facilitate access to evidence-based health care for a large number of people. Recently, researchers have started to explore the potential of smartphones in the field of e-mental health (Boschen and Casey, 2008; Ehrenreich et al., 2011; Eonta et al., 2011; Heron and Smyth, 2010; Proudfoot et al., 2013). Compared to interventions that are exclusively delivered via a device that connects to stationary internet (such as PC or laptop computer), an assimilation into the everyday life can be fostered with the use of mobile technology such as smartphones (Enock and McNally, 2014; Harrison et al., 2011; Price et al., 2014). Particularly in the case of PD, the use of mobile tools in treatment is promising, as the treatment intervenes where panic attacks take place, namely in the everyday lives of those affected (Christoforou et al., 2017; Ivanova et al., 2016; Proudfoot et al., 2013). Mobile-based interventions show advantages such as a high accessibility to the internet, independence of time and location regarding treatment delivery, provision of context-sensitive feedback, real-time data collection as well as the use of sensor technology for data collection (Heron and Smyth, 2010; Proudfoot, 2013).

However, the emerging field of m-mental health can still be described as being in its infancy as many available apps lack scientific evidence (Donker et al., 2013; Sucala et al., 2017) or show poor content quality (Singer et al., 2015). For these reasons, in addition to studies evaluating treatment efficacy, initial exploratory studies are needed for building foundations

to assess usability and feasibility of innovative tools in treatment of mental problems as well as gaining and sharing further knowledge in this field. Examples of such in-depth feasibility studies in the field of m-mental health include the work of Morrison et al. (2014) providing data (N = 13) on quantitative app usage as well qualitative interviews regarding the desktop- and app-based weight management POWeR Tracker. As one of the main results the aforementioned authors highlight the benefit of a multicomponent, hybrid intervention format. Supplementing a web-based program with a mobile application leads to higher awareness of achievement of eating and physical activity goals, which was also confirmed by qualitative evidence. Another exploratory investigation on an intervention based on Acceptance and Commitment Therapy (ACT) that integrated mobile- and desktop-based technology suggested that participants (N = 11) suggested an increase in ACT-relevant outcomes as psychological flexibility and valued action; scores on depression, anxiety, stress and global satisfaction did not change over time (Ly et al., 2012). Further, participants' experience of the intervention was investigated with the help of qualitative questionnaires indicating that the mobile application has the potential to transfer the training into the daily life of the client, while the psycho-educational part delivered via a desktop-based tool was perceived as too text-based. For further research the authors suggest an integration of mobile technology in order to increase adherence to online health trainings. Further, Morris et al. (2010) presented five case studies on an app for emotional self-awareness in order to understand participants' use of the newly developed mobile application. More examples of feasibility studies include mobile interventions for depression (Burns et al., 2011), bipolar disorder (Bardram et al., 2013; Bardram et al., 2012), schizophrenia (Depp et al., 2010) and promoting health behaviors as self-monitoring of caloric balance (Tsai et al., 2007) or understanding medication labels (Grindrod et al., 2014).

Due to tremendous potential of m-health interventions and the lack of studies in the field of PD, the aim of the present feasibility study is to explore usage, usability and acceptance of the newly developed GET.ON Panic app as part of a hybrid online training GET.ON Panic. Furthermore, we present initial clinical outcomes of the training on panic symptom severity, depressive symptoms as well additional anxiety measures and to draw conclusions for future development of mobile interventions for research and practice.

## Methods

### Participants

The 10 participants were recruited from the waiting list of interested individuals for participation in online trainings for PD. They learned about the possibility to take part in the GET.ON online training via newspaper or radio reports. The average age of the participants was 41,5 years (SD = 14,4 years, N = 10) with an equal representation in gender (five female, five male participants). With regard to the participants' ethnical background, seven are Caucasian, one is Asian and two did not make a specification. Seven of ten participants have a college degree or higher, two have finished a vocational training and one has finished secondary school. Experience with psychotherapy was mentioned by nine of the ten participants. Eight of them had received psychotherapy for PD prior to the study. Seven of the participants used an iPhone with an iOS operating system and three of them participated with an Android smartphone. For further information see Table 1. For better readability, we have decided to nickname the study participants. These names are unrelated to their real name.

Table 1
*Overview of the demographics of the 10 participants.*

| Nickname | Gender | Age | Family status | Diagnosis[c] | Smartphone |
|----------|--------|-----|---------------|--------------|------------|
| Sid | M | 38 | Married | PD, OCD | iPhone 4s[a] |
| Joy | W | 36 | Unmarried | PD/A, SAD | Sony Ericsson pro[b] |
| Ken | M | 64 | Unmarried | PD | iPhone 4[a] |
| Liz | W | 20 | Unmarried | PD/A | iPhone 4[a] |
| Amy | W | 56 | Separated | PD/A, GAD | iPhone 3GS[a] |
| Guy | M | 60 | Married | PD | iPhone 5[a] |
| Dan | M | 28 | Married | PD/A | iPhone 4 S[a] |
| Joe | M | 33 | Married | PD/A | Motorola xt890[b] |
| Yue | W | 35 | Married | PD/A | Samsung Galaxy S3[b] |
| Ash | W | 45 | Separated | PD/A | iPhone 4[a] |

PD = Panic Disorder; OCD = Obsessive Compulsive Disorder; PD/A = Panic Disorder with Agoraphobia; SAD = Social Anxiety Disorder; GAD = General Anxiety Disorder.
[a] = iOS operating system.
[b] = Android operating system.
[c] = According to SCID-I interview.

### Intervention

The GET.ON Panic app that is described and evaluated in this paper was part of the hybrid online training GET.ON Panic combining a desktop and a mobile component based on cognitive behavioral therapy (CBT) for PD. The hybrid online training consists of 6 modules with a recommendation of working on one module per week. After every module,

participants received feedback on their training progress by a trained psychologist. The first module is mainly an introduction of the training and the mobile application. Furthermore, psycho-education concerning panic, agoraphobia and avoidance are offered. In the second module, participants start with interoceptive exposure exercises in order to provoke similar bodily symptoms as in a panic attack with the intention of getting used to those symptoms. In-vivo exposure exercises are part of the third module. Participants confront themselves with their anxiety provoking situations in real life. The fourth and fifth modules focus on cognitive restructuring exercises with an emphasis on the role of irrational beliefs with regard to panic-associated topics. The sixth and last module is about relapse prevention and finally deals with an evaluation of the training in terms of attaining individual goals. Overall, the desktop components are primarily used to provide text- and video-based psycho-education as well as exercises that require extensive writing. The mobile application GET.ON Panic app consists of two main components: a mobile diary and a mobile exposure guide.

The mobile diary is used to document panic attacks and to record daily summaries. When the mobile application is started, users are presented with the main screen (see Fig. 1a) from which the desired component and function can be activated quickly. For further description of the hybrid online training see the study protocol for the RCT (Ebenfeld et al., 2014). To document a panic attack with the GET.ON Panic app, users are asked to answer four questions on a Likert-like scale from 1 to 10 (see Fig. 1b). For this purpose, we created a novel input component based on the single-dimension mood-scale presented by Morris et al. (2010). The number moves with the finger and the intensity of the background color changes in order to provide an additional visual feedback (high values have a high intensity and vice-versa). In addition, we wanted users to be able to give individual meaning to a panic event in a non-prescribed way. We anticipated that some users are more visually oriented while others tend to prefer text. Therefore, two additional options have been included in the documentation of panic events. First, we encourage users to take a photo of either the situation where the event occurred or something that is related to the situation. Second, they may enter written notes in order to remember feelings or specific aspects of the situation. For daily summaries, a fixed-schedule diary was implemented (Bolger et al., 2003). Participants were asked to choose a fixed time each day, preferably in the evening, where they reflect on the past day and fill in a daily summary. In order to visualize a client's development and progress, the application plots the daily summaries over time (see Fig. 1d).

Furthermore, the plot illustrates how using the training exercises can reduce panic symptoms by depicting, for each day, how many exposure exercises have been performed.

The exposure guide offers support for performing interoceptive and in-vivo exposures. It is constructed as a wizard, which leads the user through a sequence of steps while at the same time offering instructions and orientation (see Fig. 1c). In addition, at certain points, the user is asked to answer questions in order to measure if the exposure has been performed correctly (for example the level of anxiety, the degree of avoidance and the severity of body-symptoms). After an in-vivo exposure, users are offered feedback to see if the exercise worked and to reflect on the situation (see Fig. 1e). Furthermore, they have the possibility to take of photo of the mastered situation. Users can review these photos in a photo gallery together with the feedback and a description of the situation.
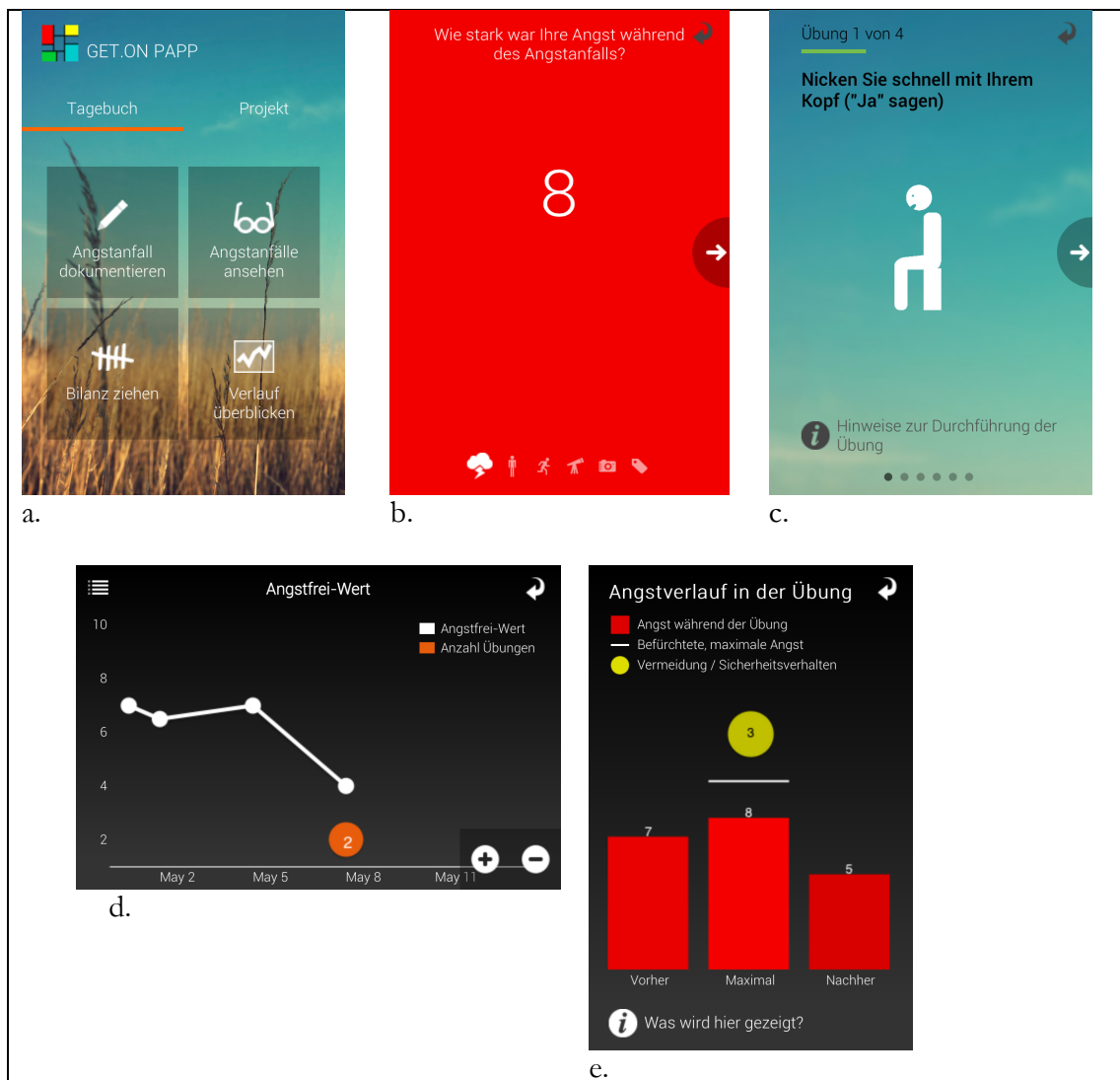
*Figure 1. Screenshots of the GET.ON Panic app.*
    a.   *The main screen of the app.*
    b.   *Rating anxiety when documenting a panic attack.*
    c.   *Introduction to an interoceptive exposure exercise.*
    d.   *Daily summary graph.*
    e.   *Feedback after an in-vivo exposure exercise.*

**Development of the app**

High credibility is crucial to facilitate behavioral change (Fogg, 2003), whereas credibility is defined as the combination of perceived trustworthiness and perceived expertise and highlights the importance of a product's visual appearance for the perceived first-hand and long-term experience (Fogg, 2003; Fogg et al., 2009). For these reasons, the GET.ON Panic app was developed in an iterative process in a multidisciplinary team of IT scientists, visual

and interaction designers and psychologists from science as well clinical practice. We started each iteration by creating a paper mockup for a specific feature that the app should fulfill. The mockup was refined until the functionality was presented to our satisfaction. Following this, we have created a functional prototype that can be run on a smartphone. In the next step, this prototype was extensively tested and gradually improved in several feedback loops in the multidisciplinary development team. Instead, we decided to use psychotherapists and researchers with experience in the treatment of PD. In addition, we conducted regular but informal tests with team members who were not directly involved in the app development. For further presentation of the app, see also Kleine Stegemann et al. (2013).

**Measures**

*Screening*

Interested individuals were screened at the beginning of the study according to in- and exclusion criteria identical to those described in the study protocol of the planned RCT (Ebenfeld et al., 2014). This screening consisted of demographic data (e.g. age, gender, education, smartphone model), the Panic and Agoraphobia Scale (PAS) (Bandelow, 1995, Bandelow, 1997) and Item 9 of the BDI-II that screens for suicidality (Beck et al., 1996; Hautzinger et al., 2006). Furthermore, the Structured Clinical Interview for DSM-IV-TR axis-I disorders (SCID-I) (Wittchen et al., 1997) was used to get a detailed sample description (e.g. presence or absence of PD, agoraphobia, other anxiety disorders and a current depressive episode). The interview was conducted by a trained interviewer via telephone (Irvine et al., 2012; Rohde et al., 1997).

*Clinical outcomes*

Panic symptoms were measured with the PAS (Bandelow, 1995, Bandelow, 1997; Bandelow et al., 2000). The PAS is a 13-item questionnaire which is divided into five subscales addressing panic attacks, agoraphobic avoidance, anticipatory anxiety, limitations in daily life, and health concerns (e.g., fear of physical harm or fear of an organic cause). These subscales can be evaluated separately or as a total score, ranging from 0 to 52. Higher scores indicate a higher level of panic symptoms. The psychometric properties of the scale are good, with Cronbach's alpha of 0.86 (Bandelow, 1995). A score of 0–8 indicated no clinical relevant symptoms, a score of 9–28 a moderate level of symptoms, and a score of 29 or higher indicated severe symptomatology (Bandelow, 1995). Agoraphobic cognitions were assessed with the Agoraphobic Cognitions Questionnaire (ACQ) (Chambless et al., 1984; Ehlers and

Margraf, 2001). The 14-item questionnaire has a total score range between 14 and 70. Internal reliability is reported as $\alpha = 0.80$ (Craske et al., 1986). Bodily sensations were measured with the Body Sensation Questionnaire (BSQ) (Chambless et al., 1984; Ehlers and Margraf, 2001), a 17-item self-report questionnaire. The total score of the BSQ ranges from 17 to 85 and has proven a good internal reliability of $\alpha = 0.87$ (Chambless et al., 1984). Agoraphobic avoidance was measured with the Mobility Inventory (MI) (Chambless et al., 1984; Ehlers and Margraf, 2001). The 27 items of the MI cover the most important agoraphobic situations. Each situation is rated for both when person is alone and when they are accompanied by someone else. The two total scores range from 27 to 135, respectively. The internal consistency is reported to be $\alpha = 0.94$ (alone) and $\alpha = 0.91$ (accompanied) (Chambless et al., 1984). Furthermore, the Hamilton Anxiety Rating Scale (HAM-A) (Hamilton, 1959; Weyer, 2005), a 14-item observer-rating was conducted. For these reasons an adaption of the structured interview guide for the Hamilton Anxiety Rating Scale (SIGH-A) (Shear et al., 2001). The total score of the HAM-A and SIGH-A ranges between 0 and 30. The interview has shown good inter-rater and test-retest reliability of $ICC = 0.99$, $\alpha = 0.86$ (Shear et al., 2001). Depressive symptoms were assessed with the well-established German version1 of the Centre for Epidemiological Studies Depression Scale (CES-D) (Hautzinger and Bailer, 1993; Radloff, 1977). The 20 items were answered on a 4-point Likert scale regarding the previous week. The total score ranges from 0 to 60. Internal consistency is reported as Cronbach's $\alpha = 0.89$ (Hautzinger and Bailer, 1993).

**Usability**

Usability of GET.ON Panic app was examined using the System Usability Scale (SUS). The ten-item scale ranging from 0 to 100 gives a an overview of subjective assessments of the usability (Brooke, 1996). A reliability analysis conducted by Bangor et al. (2008) found the internal consistency of the SUS to be Cronbach's $\alpha = 0.91$. The survey was administered only at post-trial. At the time of the study, there was no standard German translation of the questionnaire. As a consequence, we involved experts from the field to create our own German version of the SUS using back and forward translation to ensure the correct translation.

**Technology acceptance**

Research on technology acceptance is an established part of information systems science, which strives to explain factors that affect acceptance of software systems. The technology

acceptance model (TAM) and its successor TAM2 are commonly used models that are based on theory of reasoned action (Davis, 1989; Venkatesh and Davis, 2000). While the conducted pilot-study is not powered sufficiently for a full-size TAM analysis, we used the subscales to assess acceptance of our app. Specifically, these include the dimensions "Perceived Usefulness" and "Perceived Usability". Furthermore, researchers have noted that acceptance is not only motivated by extrinsic aspects but also by intrinsic factors (Davis, 1989; Heijden, 2004). For this reason, we included a third scale for the dimension "Perceived Enjoyment". We developed items for the three different scales based on the questionnaires published by Venkatesh and Davis (2000) as well as the items on perceived enjoyment as proposed by Heijden (2004). In this process, we incorporated researchers from the field of clinical psychology as well as information science. The survey was conducted at post-trial.

**Compliance to app**

To assess compliance with GET.ON Panic app, the number of interactions with the app was recorded. In this context, we defined an interaction as the activation of a function of the app by its user. Due to technical limitations, low-level interactions, such as single gestures or page transitions, have not been stored. Furthermore, it has to be noted that we did not include "view-only" interactions, such as reading the diary or looking at photos. From the recorded data, several measures were derived. First, the number of interactions per module and over the course of the intervention was used to evaluate app usage at a global level. Next, the average number of interactions per day has been calculated in order to account for varying intervention durations amongst participants. Finally, we determined the total and average number of interactions per participant to evaluate individual differences.

**User satisfaction**

User satisfaction of the training was measured with a self-designed questionnaire based on the German version of the Client Satisfaction Questionnaire (Attkisson and Zwick, 1982; Schmidt et al., 1989). The adapted version of the questionnaire consists of 8 items and the total score ranges from 0 to 32. Internal consistency of the original German version questionnaire has been reported as good (Schmidt et al., 1989).

*Feasibility interviews*

A semi-structured interview with the participants was conducted at post-trial via telephone. The interview consisted of 59 open questions covering the training in general, the specific functions of GET.ON Panic app, integration of app and online training as well as enjoyment.

**Data analysis**

All data contained answers from 8 participants and were analyzed on completer-only principals due to drop out of 2 participants. The quantitative analyses were done using R (package = "lsr") (Navarro, 2014; R Core Team, 2013). We calculated the changes in pre and post scores by performing t-tests. Furthermore, we calculated Cohen's d effect sizes for the clinical outcome measures. The qualitative data was analyzed based on thematic analysis according to Braun and Clarke (2006). For these reasons, the recorded interviews were transcribed and coded. Subsequently, all important aspects related to the research questions were identified and clustered to identify relevant topics and general patterns.

## Results

### Adherence

Eighty percent of the participants completed the questionnaires and finished the training after lesson 6. Two participants (Yue and Ash) dropped out after module 2 and module 5 respectively and did not take part in the post assessment. We were not able to reach them anymore.

### Clinical outcomes

Using two-sided unpaired t-test we did not find a significant change pre and post intervention for any clinical outcome measures. Table 2 gives an overview of the data.

Table 2
*Clinical outcome (n=8)*

| | M(SD) pre | M(SD) post | M(SD) pre-post | t-test[a] | Effect size[b] |
|---|---|---|---|---|---|
| PAS | 17.25 (6.98) | 13.75 (5.42) | 3.5 (6.05) | $t_{(df)}$ = 1.12 NS | d = 0.56 |
| HAM-A | 17.62 (7.41) | 11 (8.68) | 6.62 (5.29) | $t_{(df)}$ = 1.64 NS | d = 0.82 |
| ADS | 21.88 (12.04) | 15.88 (12.67) | 6 (10.93) | $t_{(df)}$ = 0.97 NS | d = 0.49 |
| ACQ | 1.71 (0.50) | 1.39 (0.42) | 0.32 (0.36) | $t_{(df)}$ = 1.39 NS | d = 0.70 |
| BSQ | 2.58 (0.76) | 2.26 (0.54) | 0.32 (0.55) | $t_{(df)}$ = 0.96 NS | d = 0.48 |
| MI-Al | 2.02 (0.59) | 1.81 (0.56) | 0.20 (0.34) | $t_{(df)}$ = 0.71 NS | d = 0.35 |
| MI-Ac | 1.63 (0.58) | 1.55 (0.50) | 0.08 (0.23) | $t_{(df)}$ = 0.31 NS | d = 0.15 |

PAS=Panic and Agoraphobia Scale; HAM-A=Hamilton Anxiety Rating Scale; ADS=Allgemeine Depressions-Skala; ACQ=Agoraphobic Cognitions Questionnaire; BSQ=Body Sensation Questionnaire; MI-Al=Mobility Inventory (alone); MI-Ac=Mobility Inventory (accompanied). [a] =Independent two-sided *t*-test. [b] =Cohen's d pre-post (within) (0.30 for small effect, 0.50 for medium effect, 0.8 for large effect) ; NS=Not significant.

**Usability**

Results from the System Usability Scale are summarized in Table 3. The mean score of 84.06 indicates that there have been no serious usability issues. According to Bangor et al. (2008), GET.ON Panic app shows a good usability that is well within the acceptable range. The mean scores for all items were above midpoint of the scale for positive and below midpoint for negative items (Table 4). Of note is that participants found the app generally easy to learn and easy to use. On the other hand, item 4 has a mean score of 2.38 which indicates that some participants experienced technical issues. This is in line with problems reported by clients to our technical support (Table 5). All problems except the touch issues reported by one participant (Joy) could be solved and participants were able to continue using the app.

Table 3
*System Usability Scale (n=8), range 0-100.*

| Participant | SUS Score |
|---|---|
| Sid | 97.50 |
| Joy | 82.50 |
| Ken | 77.50 |
| Liz | 100.00 |
| Amy | 92.50 |
| Guy | 62.50 |
| Dan | 90.00 |
| Joe | 70.00 |
| | M=84.06 (SD=13.36) |

Table 4
Item ratings of the System Usability Scale (n=8).

| Item | Mean (SD) |
|---|---|
| 1. I think that I would like to use this app frequently. | 4.00 (0.76) |
| 2. I found the app unnecessarily complex. | 1.50 (0.76) |
| 3. I thought the app was easy to use. | 4.38 (0.52) |
| 4. I think that I would need the support of a technical person to be able to use this app. | 2.38 (1.69) |
| 5. I found the various functions in this app were well integrated. | 4.13 (0.83) |
| 6. I thought there was too much inconsistency in this app. | 1.50 (1.07) |
| 7. I would imagine that most people would learn to use this app very quickly. | 4.38 (0.74) |
| 8. I found the app very cumbersome to use. | 1.25 (0.71) |
| 9. I felt very confident using the app. | 4.50 (0.76) |
| 10. I needed to learn a lot of things before I could get going with this app. | 1.13 (0.35) |

*Note:* All items rated on 1-5 Likert scale with 1=strongly disagree and 5=strongly agree.

Table 5
*Technical problems as reported by participants (n=8).*

| Participant | Technical Problem(s) |
|---|---|
| Sid | - |
| Joy | Touch gestures did not work properly for in-vivo exposures. |
| Ken | App became unresponsive after accidentally activating the copy function. |
| Liz | - |
| Amy | App crashed because there was no space left on device. |
| Guy | App terminated a few times during an in-vivo exposure exercise. |
| Dan | - |
| Joe | Needed to re-install app after device was reset. |

**Technology acceptance**

The results from the assessment of technology acceptance for GET.ON Panic app are illustrated in Table 6. In general, participants scored high on all items of the TAM survey. They did not only find the mobile application to be useful for the training (subscale "Perceived Usefulness", M = 6.13, SD = 0.75, Likert scale 1–7), but also indicated that they enjoyed using the app (subscale "Perceived Enjoyment", M = 5.89, SD = 0.91, semantic differential 1–7). Furthermore, the score for perceived usability (M = 6.09, SD = 1.24, Likert scale 1–7) is congruent with the results from the system usability scale.

Table 6
*Results from the TAM survey (n=8).*

| Subscale: Perceived Usefulness | M=6.13 (SD=0.75) |
|---|---|
| 1. The app makes the training more effective for me. | M=6.13 (SD=1.13) |
| 2. The app makes it easier for me to implement the training. | M=6.13 (SD=0.83) |
| 3. The app makes the training more intense for me. | M=6.38 (SD=0.52) |
| 4. I find the app to be useful for the training. | M=6.00 (SD=1.07) |
| 5. The app makes the training easier for me. | M=6.00 (SD=0.76) |
| **Subscale: Perceived Enjoyment** | **M=5.89 (SD=0.91)** |
| 6. Boring – Interesting | M=6.38 (SD=0.74) |
| 7. Unpleasant – Pleasant | M=5.13 (SD=1.36) |
| 8. Dull – Exciting | M=6.00 (SD=0.93) |
| 9. Disgusting – Enjoyable | M=6.00 (SD=1.07) |
| **Subscale: Perceived Usability** | **M=6.09 (SD=1.24)** |
| 10. My interaction with the app is clear and understandable. | M=6.00 (SD=1.41) |
| 11. Interacting with the app does not require a lot of mental effort. | M=6.00 (SD=1.41) |
| 11. I find the app to be easy to use. | M=6.25 (SD=1.16) |
| 12. I find it easy to get the app to do what I want it to do. | M=6.13 (SD=1.25) |

*Note:* Items for perceived usefulness and perceived usability rated on 1-7 Likert scale with 1=strongly disagree and 7=strongly agree; For perceived enjoyment, semantic differentials have been used with a scale from 1-7.

**Compliance to app**

The eight participants spent a mean of 51.88 days in the training (SD = 12.11). During this time, they used GET.ON Panic app on average 1.56 (SD = 0.96) times per day. The use of individual app functions varies amongst participants with daily summaries and interoceptive exposures being the most popular parts. On the other hand, the function for in-vivo exposures was not well received and the number of documented panic events seems to be rather low (see Table 7).

Table 7

*App use for clients (n=8).*

| Participant | Diary[1] (n) | Daily Summary[2] (n) | Daily Summary Compliance[3] | Interoceptive Exposure[4] (n) | In-vivo Exposure[5] (n) | Average daily use[6] (n) |
|---|---|---|---|---|---|---|
| Sid | 9 | 36 | 86% | 65 | 0 | 2.62 |
| Joy | 4 | 7 | 14% | 5 | 0 | 0.31 |
| Ken | 2 | 6 | 15% | 125 | 0 | 3.24 |
| Liz | 2 | 39 | 83% | 1 | 1 | 0.91 |
| Amy | 8 | 41 | 79% | 29 | 0 | 1.50 |
| Guy | 6 | 50 | 76% | 43 | 9 | 1.64 |
| Dan | 4 | 33 | 45% | 24 | 0 | 0.86 |
| Joe | 0 | 36 | 86% | 22 | 0 | 1.38 |
| Mean (SD) | 4.38 (3.11) | 31.00 (15.95) | 60.50 (31.31) | 39.25 (40.18) | 1.63 (3.16) | 1.56 (0.96) |

*Note*: [1]Number of reported anxiety related events during the training period (e. g. panic attack or avoidance behavior). [2]Number of completed daily summaries within the training period. [3]Compliance is reported as percentage of the number of days in training on which the participant filled out the daily summary with the app. [4]Number of completed interoceptive exposure exercises during the training period. [5]Number of completed in-vivo exposure exercises during the training period. [6]Average daily use, calculated as the sum of interactions divided by number of days in training.

Fig. 2 shows that, on average, app use was highest in the second module (2.34 times per day) and remained – at a slightly lower level – fairly constant for modules three to six. During the last module, however, the app was used significantly less by all participants. Examination of app use and clinical outcomes shows no significant relation between average use per day and clinical outcomes (Fig. 3). This is illustrated, for example, by Sid, who used the app 2.62 times per day but improved less than Liz, who used the app only 0.91 times per day. The PAS score of Ken, who performed the most interoceptive exposure amongst all participants (125 times) and also used the app most often even increased by 5 points.
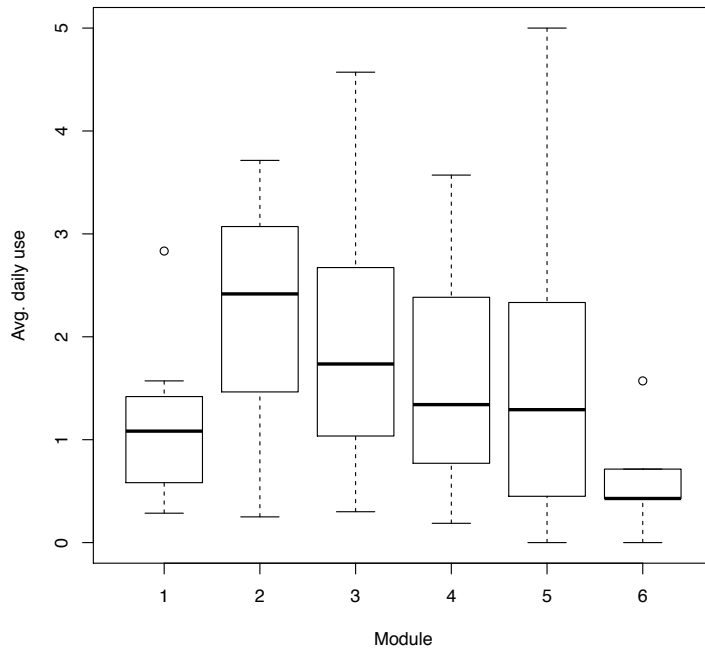
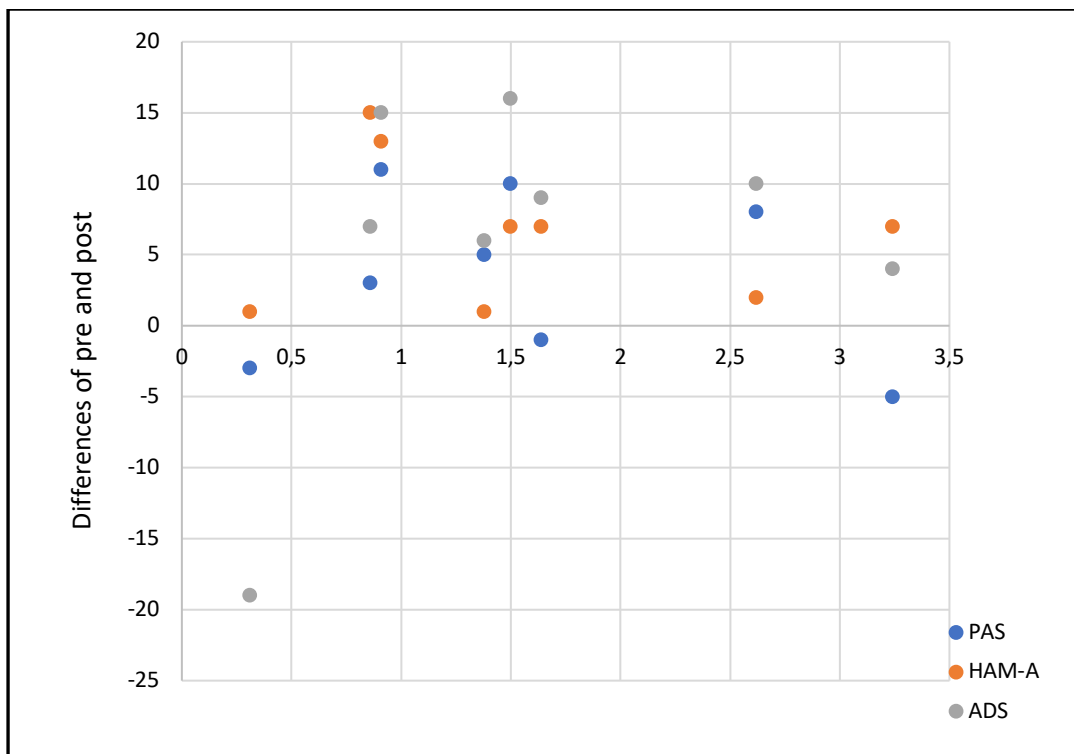*Figure 2. Average daily use app over the course of the training (n=8).*



*Figure 3. App use and clinical outcomes (n=8).*

**User satisfaction**

All participants scored high on the user satisfaction questionnaire with a mean of 30.13 (SD = 1.64). Given that the maximum achievable score is 32, we can assume a high level of satisfaction of the participants with the training in general.

**Interviews**

Based on thematic analysis (Braun and Clarke, 2006) five key themes were identified. Visual feedback and photo function were themes that directly address the functions of the app. Everyday suitability, usability (design) and interaction of app and online training were also functional but from a more general perspective. In addition, motivation and self-efficacy were clustered as intrapersonal themes.

*Feasibility*

The training without the mobile component was described as difficult to complete "because you just do not have the computer with you" as Joy stated. The exposure exercises on the app were perceived as "feasible" (Guy), "easy" (Amy) and "comprehensible" (Joe). One of the perceived advantages by Liz was that "the anxiety provocation exercises [interoceptive exposure exercises] could be done in real time by means of the app". Joy was not able to integrate the exercises in her daily life due to technical problems (as discussed in the usability section). Six of the eight participants would have preferred a reminder for the exercises and daily summary. Most of the participants were able to fill in the daily summary most of the time (see compliance to app). In the following, reasons for non-compliance to the diary will be specified. Joy reported that she forgot to fill in the diary "if there wasn't an anxiety event on this day or because I was distracted by other things". Ken also mentioned time-related problems that lead to forgetting the daily summary. Regarding the registration of anxiety events the participants reported problems with performing this task. Reasons for this were "I haven't had any panic attacks at all during the course of the training" (Joe) or "during the moment of panic, I didn't have a clear head and the time for this" (Joy). Regarding the in-vivo exposures a typical problem was that participants forgot to finish the exercise by pushing the 'finish' button with the consequence that the data was not recorded. Others reported that the app functions as tutorial and motivation, but the actual in-vivo was performed in a non-structured way without the app. With regard to the interoceptive exposure participants reported less problems with performing this task according to the app. Only Dan stated that "it became annoying to answer all the questions twice a day".

*Motivation*

In the interview all participants indicated that motivation was an important factor of the mobile application. Dan described that "technical gadgets are per definition very motivational". Guy stated: "Using the app was fun because I am an app-oriented person". Especially in terms of conducting the interoceptive exposure exercises the mobile application was perceived as valuable. All of them stated that they would not have done the exercises that often without the app. One perceived the app as "mental support" during the exercises and "The fact that you can see what you have done is very motivating.". Regarding motivational elements in the app the participants expressed contrary opinions. Three participants said that they would appreciate to have more motivational elements. "More motivational elements would be a good loosening up for the training." Two of the eight participants experienced the motivational elements (such as the photo function) as "way too much" and "not desirable".

*Usefulness*

One objective of the self-help training was to provide people who are suffering from panic with a better understanding of their anxiety. Nearly all participants reported that especially the interoceptive exposure exercises lead to a better understanding of how the body reacts during a panic attack. "You can make the difference with interoceptive exposure exercises. Also, the daily summary facilitates the own estimate", as one participant states.

*Visual feedback*

Five interviewees reported that they liked the visual representation of the daily summaries and that it helped them to become more aware of their course of panic attacks. One said "that the perception of an anxiety attack is quite different at the moment while it happens and afterwards" and another one stated "retrospectively, I realized that nothing frightening would really happen". Dan experienced the visualization of daily summaries as "reasonable but without added value" due to the fact that he knew "how the course of anxiety will look like". Only Guy said that "the visual feedback was not that helpful. A simplified visualization with bar charts would be preferable". The graphical representation of the exposure exercises was also perceived as useful by nearly all of the users. "The graphical feedback of the exposure exercise was helpful to understand 'the thing as a whole'". One remark of Dan was that he would have preferred all questions on a single page.

*Photo function*

The photo function as part of the documentation of the anxiety events as well during the in-vivo exposure lead to controversial statements. Most of the participants stated that they understood the meaning of the photo function but they did not use it. In the interviews we found explanations like "taking a picture wouldn't have a benefit" or "a nice gadget, but I wasn't able to take a picture of the anxiety provoking stimulus" or "anxiety events weren't catchable enough to capture in a photo" or "taking pictures wasn't important for me, the graphical feedback was more important to me". Another one said "I just took a picture, it was a symbolization of the moment - how I felt there". All participants who found it difficult to take a picture of an anxiety provoking stimulus agreed that they would have preferred to take a picture of a positive association which was not related to an anxiety-trigger.

*Interaction of app und online training*

One part of the interview focused on the integration of the app and the browser-based training part into a hybrid online training format. All participants said that the combination of both was overall coherent and very motivational. As a suggestion for improvement "it would be great if you would open the app and automatically see the exercises concerning module 3" (Joe).

## Discussion

Previous research has highlighted the potential of smartphones to treat mental health problems (Boschen and Casey, 2008; Ehrenreich et al., 2011; Eonta et al., 2011; Heron and Smyth, 2010; Proudfoot et al., 2013). In this paper, we presented the mobile application GET.ON Panic app and examined its development, feasibility, usability, technology acceptance and first indices on clinical effectiveness amongst 8 participants suffering from PD symptoms.

**Principal findings**

Below we discuss the most important findings that can be drawn from this study.

*App development*

We developed the mobile application with an interdisciplinary team of researchers and clinicians from the fields of psychology, computer science and visual design in an iterative process. We have perceived this as a very efficient way of working. Clear areas of

responsibility, different perspectives and frequent exchanges led to a common understanding of the objectives and little "frictional losses".

**Feasibility and usability**

Most participants viewed the GET.ON Panic app as a feasible means of training. The usage was relatively high with daily summaries and interoceptive exposures exercises as the mostly used and most valued parts of the app. All participants stated they would not have done these exercises that often without the app. The app thus seems to enhance adherence to the training and to fulfill a motivational function. High scores on user satisfaction, usability and technology acceptance support these findings.

However, some parts of the app offer room for improvement. Overall, two components of the app were perceived as difficult. First, the participants reported problems with performing the real-time registration of anxiety events. Reasons for this could be that they currently do not suffer from panic attacks at all. For this case, they received the instruction instead to register the avoidance behavior whenever it occurs. However, this instruction seems difficult to follow per se, since avoidance is usually not conscious behavior and therefore difficult to notice and register. As further explanation it can be stated that registering a panic attack while actually having a panic attack is perceived as difficult. Participants reported they were too excited to enter data immediately and registering in this case was not perceived as supportive. Second, performing in-vivo exposures guided by the app led to difficulties. This exercise was introduced in one of the modules of the browser-based training. Here, the participants have to build their anxiety hierarchy by ordering their anxiety-provoking moments from weak to strong. Further, they have to enter this hierarchy in the app again. This was perceived as ineffective. A synchronization of data between app and training was desired in order to enhance the usability. In addition, it seems that the instruction of the app was difficult to follow. After successful exposure task, the participants were asked to stop the exercise on their smartphone display. However, it is suggested that many participants forgot this step due to excitement while and after exposure.

Using the app seems to facilitate daily routines during the training such as performing interoceptive exposure exercises or monitoring symptoms as overall anxiety or mood. In contrast, measuring data that is less predictable and more event-related (e.g. as in-vivo exposures or monitoring panic attacks) was perceived as more difficult. These perceptions

were in line with the findings of Morrison et al. (2014). They stated that their POWeR tracker app was associated with greater usage for specific, repetitive behavior.

*Integration in daily life*

All participants said to perceive the combination of both, a mobile tool and a browser-based training as coherent and very motivational. In particular, elements of the app, such as (interoceptive) exposure exercises and receiving graphical feedback after performing this task helped them to get an understanding of their bodily sensations during anxiety moments. As an idea for improvement some participants only wished one reminder for the daily recurring exercises in order to ensure a better integration of these exercises in their daily routines. Other elements led to more controversial statements. For example, the usage of the photo function as part of the documentation of the anxiety events or during the in-vivo exposure has not added any therapeutic value to the participants. Most of them did not use it or consider it as a fun gadget. In contrast to our initial assumptions, it seems that a photo function is not an effective means to enhance the transfer of the training into the daily-lives of the participants.

*Effects of app on clinical outcomes*

In view of the study design, we can neither make reliable statements about the clinical effectiveness of the app nor of the hybrid online training and its mechanisms of change. However, due to the fact that most participants improved on the clinical outcomes like panic, anxiety and depressive symptoms, albeit, non-significant overall, we assume the hybrid training has the potential to reduce panic symptoms as well as further clinical outcomes such as depression. Since we did not find any correlation between clinical improvement and app usage, we cannot further specify the added value of the app compared to browser-based training alone in terms of clinical efficacy. Moreover, in the recent meta-analysis of Andrews et al. (2018), including only browser-based trainings for PD (e.g. Carlbring et al., 2006; Ballegooijen et al., 2013; Wims et al., 2010), a large mean effect size of hedge $g = 1.31$ was found, which also indicates that the benefit of the app in terms of clinical efficacy needs further investigation.

**Strengths and limitations**

One strength of this study is the mixed method design with taking qualitative and quantitative data into consideration. This allows us to draw conclusions about how affected people rated,

used and interacted with an app for PD. As a limitation, this exploratory study design is not able to meet the demand for generalizability of the results to a larger population. Furthermore, conclusions about the clinical effectiveness are also not possible due to a missing control group and insufficient power of the study. As a final remark, it should be noted that two of the ten participants dropped out of the study without giving any reasons. We were not able consider their opinions on feasibility. This could bias the present interpretation of the results.

**Future work**

As a short-term implication we would like to implement minor improvements such as layout issues or integration of a prompts for entering the daily summaries. Looking further ahead, the input of data should be facilitated in the long term, especially at times when participants are in high states of arousal, as it is common during panic attacks or in vivo exposures. In these moments it may be inconvenient to enter data via the touchpad keyboard. To improve usability, data entry could be done using the integrated voice recorder that transmits voice-to-text. Furthermore, the current app has not yet explored the potential of integrated context sensors. For further long-term app development, it would be worthwhile to use GPS data to provide intelligent context-sensitive exposure tasks. People would become informed via an app notification when there is a previously defined anxiety-provoking location close to them, as, for example, a shopping mall or a high tower. They would be invited to perform an exposure task in real-time and real-place environment. This gamified component might foster the motivation of clients. As a final note on the development procedure of a hybrid online training, we favour an automatic synchronization of the entered data between the mobile app and the browser-based training to avoid the need for duplicate input on both devices and instead allow a continuous training process with an improved usability. As closing general remark when planning to develop a hybrid online training, we recommend an automatic synchronization of entered data between the mobile app and the browser-based training to avoid taking double entrees and instead offer a consecutive training process. Finally, with regard to future research an RCT is necessary to assess the clinical efficacy of the GET.ON Panic app as part of a hybrid online training.

**Conclusion**

The combination of quantitative and qualitative data leads to further insights into how participants use a health care app. Findings from this study suggest that supplementing an

iCBT training for PD with a mobile application has the potential to improve adherence, usability, usage as well clinical outcome of the training. From a patient's perspective, using the app seems fun, is engaging and facilitates daily routines during the training such as performing interoceptive exposure exercises or monitoring anxiety or depressive symptoms on a daily basis. In contrast, measuring data that is less predictable and more event-related (e.g. in-vivo exposures or monitoring panic attacks) was perceived as more difficult. With regard to further app development, this leads to the idea that the input of data during excitement, for example during panic attacks or in-vivo exposure exercises should be less effort for the individual. This can be achieved, for example, by entering data via voice and not via typing on the smartphone's touchscreen. Furthermore, the integration of intelligent context-sensitive tools, such as prompting real-time content in relevant moments could lead to further improved usage of the app. Finally, a following RCT is necessary to address this research question.

## Funding

## Author contributions

All authors contributed to the study design. LE, DL, DE, HR and MB developed the hybrid online training for treating people with PD with or without agoraphobia (GET.ON Panic). SKSt developed the app (GET.ON Panic app). BF supervised the technical aspects of the intervention. LE and SKSt performed the statistical analyses and drafted the manuscript. DL and MB revised the manuscript. All authors read and approved the final manuscript.

## Declaration of competing interest

DL, DE and BF are shareholders, LE is an employee of the transfer institute (GET.ON Institute) that currently commercializes the GET.ON Panic training. However, during developing and evaluating the app and the hybrid online training GET.ON Panic the company was not yet incorporated.

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# Kapitel 3: Studienprotokoll GET.ON Panik

**Efficacy of a hybrid online training for panic symptoms and agoraphobia: study protocol for a randomized controlled trial**

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## Abstract

### Background

Recently, internet-based interventions have been proposed as effective treatments for people with panic disorder (PD). However, little is known about the clinical effects of integrating mobile technology into these interventions. Because users carry their smartphones with them throughout the day, we hypothesize that this technology can be used to significantly support individuals with monitoring and overcoming their PD symptoms. The aim of the present study is to evaluate the efficacy and cost-effectiveness of a newly developed hybrid intervention that combines internet/PC with smartphone delivery to treat the symptoms of PD. The intervention is based on cognitive behavioral therapy and consists of six modules over a total of six weeks.

### Methods/Design

A two-arm randomized controlled trial (RCT) will be conducted to evaluate the effects of a hybrid online training module for PD. Based on a power calculation (d =0.60; 1-β of 80%; α =0.05), 90 participants with mild to moderate panic symptoms with or without agoraphobia (as assessed by the Panic and Agoraphobia Scale) will be recruited from the general population and randomly assigned to either the intervention group or a six-month waitlist control group. The primary outcome measure will be the severity of panic symptoms. Secondary outcomes will include depression, quality of life, and an observer-based rating of panic severity. Furthermore, data regarding acceptance and the usability of the smartphone app will be assessed. Assessments will take place at baseline as well as eight weeks, three months, and six months after randomization. Moreover, a cost-effectiveness analysis will be performed from a societal perspective. Data will be analyzed on an intention-to-treat basis and per protocol.

### Discussion

To our knowledge, this RCT is one of the first to examine the efficacy of a hybrid online training for adult PD. This study seeks to contribute to the emerging field of hybrid online training. If the intervention is efficacious, then research on this hybrid online training should be extended. The cost-effectiveness analysis will also indicate whether online training is an economical tool for treating PD among adults.

**Trial registration**

German Clinical Trial Register: DRKS00005223 (registered on 15 August 2013).

**Keywords**

Panic disorder; Agoraphobia; Sub-clinical; Internet; Mobile; Smartphone; Hybrid

## Background

Panic disorder (PD) is characterized by recurrent, unexpected panic attacks and a persistent worry about future panic attacks [1]. With a 12-month prevalence of 1.8% among adults, PD is one of the most common anxiety disorders [2]. In addition, sub-threshold cases have been estimated to be even more prevalent, with between 10 and 16% of the population experiencing a panic attack at some point during their lifetimes [3]. PD (with or without agoraphobia) is associated with a high psychiatric comorbidity, lower quality of life, and severe work impairment [4,5], and also places a significant burden on healthcare systems [2,6].

Psychotherapeutic treatments such as cognitive behavioral therapy (CBT) are effective for PD [7]. However, only 16.7% of people who suffer from anxiety disorders seek help from a mental health professional, and of these individuals, only 21.3% receive CBT, which is arguably the most effective treatment [8]. The reasons for this low endorsement of effective PD treatments include a lack of psychoeducation, a fear of stigmatization, and structural barriers such as a lack of access to adequate treatments [9,10].

Interventions delivered via the internet have been proposed as a helpful method to overcome such barriers and facilitate access to empirically validated treatments [11,12]. Although internet-based interventions based on CBT are effective at treating adult PD [13-16], one drawback of this method (compared with traditional face-to-face treatments) is the lack of direct support from a therapist throughout the course of treatment, particularly during exposure exercises. This lack of direct support from a therapist might increase the risk of clients not fully complying with the treatment, or dropping out of treatment completely. Studies that evaluate online trainings with self-exposure elements consistently report particularly high dropout rates [17,18].

One potentially promising method to enhance the adherence to, and efficacy of, internet-based interventions for PD might be to complement interventions with components that are delivered through clients' smartphones. Mobile components might assist patients in overcoming several limitations of traditional desktop- and laptop-based interventions. For example, these barriers might include situations in which the clients start to engage in exposure exercises in their natural environment (as is typical for *in vivo* exposure exercises) and are subsequently required to leave their desktop PCs or laptop. This results in a dilemma

– either exposure exercises are exclusively conducted at the client's desk or they are conducted without the device and therefore lack support during the exposure exercises. Consequently, clients are more likely to disengage from the intervention. In contrast, clients often carry their smartphones with them in almost any situation, and they might support clients in successfully completing the intended exposure exercise [19-21]. Moreover, when desktop PCs or laptops are used to monitor symptoms of PD to identify factors that cue panic attacks and avoidance, clients typically use daily or weekly electronic diary entries, which are likely biased by memory effects because clients must complete these diaries retrospectively and not in real-time [22-28]. In contrast, a mobile-based PD intervention tool can be used to assess the symptoms of PD in real-time through ecological momentary assessment (EMA) approaches [29-33]. Finally, a PC-based program can only prompt appropriate coping responses when the PC is on and clients are near it. Therefore, it is not available in other situations of their daily lives in which they inevitably encounter stimuli that trigger the symptoms of PD. In contrast, a mobile device that is nearly always on, or near, the client can be used as an ecological mobile intervention (EMI) device and prompt coping responses, potentially those that have been specifically identified as effective for the individual based on the EMA function of the device. Despite these advantages, no data are currently available regarding the efficacy of online-based interventions for PD that integrate a mobile component.

We developed the GET.ON PANIC intervention for adult PD. This intervention integrates desktop and mobile components into a hybrid online intervention based on CBT for PD. The desktop component is primarily used to provide text- and video-based psychoeducation, as well as exercises that require participants to write extensive texts (for example, in a cognitive restructuring module), which is difficult to do on smartphones. The mobile component is used to guide clients through self-monitoring and self-exposure tasks. To evaluate the efficacy and cost-effectiveness of GET.ON PANIC, we will conduct a randomized controlled trial (RCT).

## Methods/Design

### Study design

We will conduct an RCT with two arms: an internet-based self-help intervention supported by a mobile application with minimal guidance from a coach (GET.ON PANIC), and a

waitlist control group who will receive the intervention after a six-month follow-up assessment. Assessments will be conducted prior to randomization, at post-treatment (eight weeks), as well as at the three- and six-month follow-up assessments (see Figure 1). The Ethical Committee of Marburg approved this study (number: 2013-23 K), and it was registered with the German Clinical Trial Register (registration number: DRKS00005223).

**Enrollment**

Assessed for eligibility

Screening

Exclusion:
- PAS < 9, > 28
- Suicidal risk (BDI-II suicidal item > 1, SCID-I)
- Psychosis, dissociation, trauma, physical contraindication
- Current psychotherapeutic treatmeant / being present on waiting list for such treatment

Baseline assessment (*t0*)

Randomization (*N* = 90), stratified for diagnosis (clinical vs. subclinical, PD with agoraphobia vs. PD without agoraphobia)

**Allocation**

Intervention group receives GET.ON PANIC

Waitlist control group

**Follow-up**

Post assessment (*t1*): 8 weeks after randomization

Post assessment (*t1*): 8 weeks after randomization

Follow-up assessment (*t2*): 3 months after randomization

Follow-up assessment (*t2*): 3 months after randomization

Follow-up assessment (*t3*): 6 months after randomization

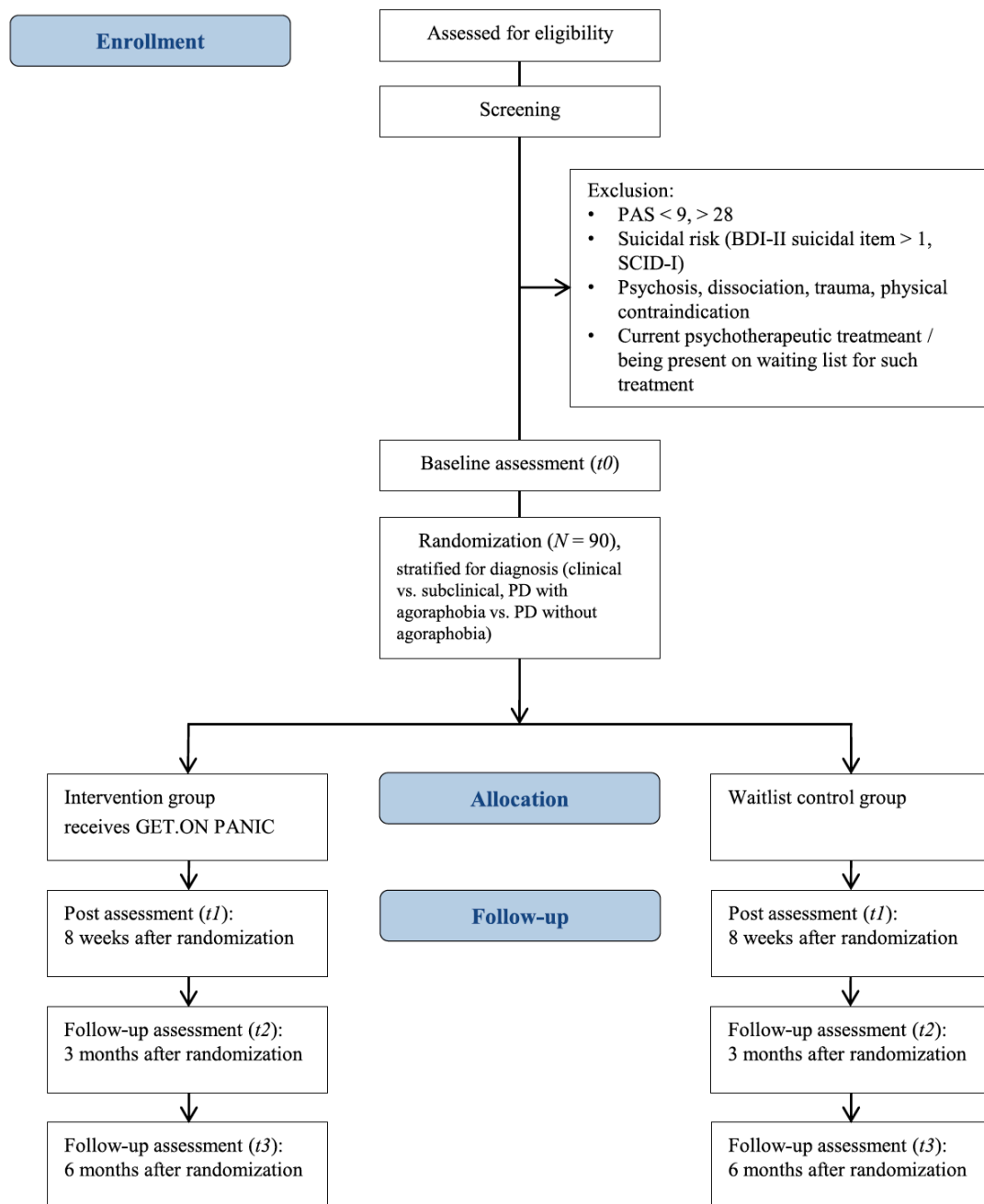Follow-up assessment (*t3*): 6 months after randomization

**Figure 1 Overview of study procedure.** BDI-II, Beck Depression Inventory II; PAS, Panic and agoraphobia scale; SCID-I, Structured clinical interview for DSM-IV Axis I Disorders.

**Study population**

The study population will consist of a community sample of adults who suffer from mild to moderate panic symptoms. The inclusion criteria are the following: experiencing mild to moderate panic symptoms as assessed by the Panic and Agoraphobia Scale (PAS, score range: 9 to 28) [34,35], being 18 years or older, having panic as the primary concern for seeking help, and having internet and smartphone access. Although both iOS™ and Android™ devices will be supported, the GET.ON PANIC APP will not run on entry-level smartphones with small screens and low memories. Therefore, the minimum system requirements are an iPhone™ 3GS or a comparable Android device. With respect to the operating system, iOS 6, iOS 7, and Android 2.3 or newer will be supported. Furthermore, because the mobile application periodically uploads data to our servers, we recommend that participants have a data plan to avoid unnecessary costs. The exclusion criteria for this study are the following: experiencing too mild (PAS score 0 to 8) or too severe (PAS score 29 to 52) panic symptoms; receiving current psychological help for anxiety problems or being on a waitlist for psychotherapy; having physical health problems assessed via self-report that prevents participants from engaging in self-exposure, as recommended by an established German guideline for treating people with PD and agoraphobia [36]; currently having posttraumatic stress disorder or psychotic or dissociative disorders assessed via self-report and clinical interview; and having current suicidality, as measured by a score above 1 on item 9 of the Beck Depression Inventory II (BDI-II) [37,38] and question A9 of the Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I) [39]. In the event that potential participants are excluded because of suicidal ideation or intention, the exclusion procedure will be managed as determined by an established suicide protocol. All excluded participants will be contacted via email and provided with information regarding where they can obtain appropriate help.

**Sample size**

The sample size for this study is based on the meta-analysis of self-help treatments for anxiety disorders by Haug *et al.* [13]. An effect size of d =0.83 was derived for PD after comparing the self-help group with the waitlist/placebo group. Because hybrid online training was not integrated into the meta-analysis, we chose a conservative estimation of d =0.60. To examine the efficacy of GET.ON PANIC with a two-tailed t-test ($\alpha$ =0.05; 1-$\beta$ =0.80), a sample of

45 participants will be needed for each group. Thus, the total sample size for this study will be 90 participants.

**Randomization**

We will use the computer program DatInf RandList Version 1.2 (DatInf GmbH, Tübingen, Germany) [40] to randomize participants into either the intervention group or the waitlist control condition. This random assignment will be stratified for clinical or subclinical symptomatology, as well as the presence or absence of agoraphobia.

**Procedure**

Participants will be recruited from the general population via an online health center website postings in anxiety- and panic-related online forums, and newspaper articles about the research project. Participants will receive an email with detailed information about the study. Afterwards, participants will be invited to complete a screening questionnaire to evaluate their study eligibility. Participants will then have access to the online training platform via their email address (as their username) and a self-selected password. If participants meet the eligibility criteria, they will receive an ID number. Participants can then opt into study participation by reading, signing, and returning the informed consent document. Participants will then receive a link to complete the baseline questionnaires. After completing the baseline questionnaires (t0), participants will be invited to take part in a telephone interview. This interview has two purposes. The first is for a trained interviewer to conduct a diagnostic interview (SCID-I) to provide a detailed sample description [41,42]. The second is to conduct an observer rating of anxiety symptoms using the Hamilton Anxiety Scale (HAM-A) [43] to strengthen the robustness of the self-report measures. Assessors blind to the participant treatment condition will conduct all observer-based ratings. The post-treatment measurement (t1) will be assessed eight weeks after randomization. Follow-up measures will be conducted at three months (t2) and six months (t3) after randomization. All questionnaires at the baseline, post- and follow-up assessments are self-reported and conducted via the internet, with the exception of the observer rating HAM-A, which will be performed at t0 and t1 via telephone. The waitlist control group will receive the treatment after t3.

**Intervention**

GET.ON PANIC is a hybrid internet-based self-help intervention with minimal therapeutic guidance based on CBT principles [18,44-46]. The hybrid online training consists of two components: a browser-based section (desktop PC or laptop) and a mobile application (smartphone app). The intervention is divided into six modules: psychoeducation, interoceptive exposure, *in vivo* exposure, two modules of cognitive restructuring, and relapse prevention (see Table 1). Using responsive web design, participants can use the program on a desktop PC, a laptop, a tablet, or a smartphone. An integrated read-aloud function allows participants to follow the lessons via audio narration. The app addresses interoceptive and *in vivo* exercises as well as diary and relaxation exercises. Detailed information about the development of the app can be found in the paper by Kleine Stegemann *et al.* [47]. In the first module, participants will receive an overview of the different modules and the practical procedure of the online training. Information about PD will be provided, and personal goals will be defined. In addition, a mobile diary will be introduced to the participants. The emphasis of the second module is interoceptive exposure. The theoretical background of the relationship between bodily symptoms and anxiety will be provided in an interactive way with videos and writing exercises. The app contains three interoceptive exposure packages, each consisting of four different tasks. In module three, participants will rank their individual anxiety provoking situations in a hierarchy before beginning the app-assisted *in vivo* exposures (see Figure 2). In addition, participants will continue with the second of the interceptive exposure exercises, which address dizziness. The fourth module concerns cognitive restructuring. Participants will deal with the maladaptive relationships among situations, cognitions, and emotions. In addition, participants will continue with interoceptive and *in vivo* exposures. In module five, participants will engage in advanced cognitive restructuring, where they analyze their thinking patterns, identify their cognitive distortions and thinking errors, challenge their thoughts associated with panic, and replace their maladaptive thoughts with more constructive cognitions. Participants will continue to practice interoceptive and *in vivo* exposures for homework. The sixth and final module is related to relapse prevention. Participants will have the opportunity to reflect, summarize, and evaluate the online training as well as their progress toward achieving their predefined goals. Participants will work towards coping prior to experiencing anxiety-provoking events that might occur in the future by making two plans: one to identify early warning signs and one for dealing with difficult life circumstances. Furthermore, participants will be trained in breathing and muscle

relaxation exercises to learn adequate coping strategies for daily stressors. Audio-based relaxation exercises will be available to the participants in both short and long formats on the app.

**Table 1 Overview of sessions**

| Week | Content and homework | |
|------|------------------------|---|
| | **Browser:** | **Mobile:** |
| 1 | Psychoeducation: | Daily diary |
| | Information about panic | Registration of current panic event (event-based) |
| | Defining goas of training | Daily summary of panic, avoidance, and mood |
| | Setting up a reward list | |
| 2 | Interoceptive exposure: | Respiratory interoceptive exposure exercises |
| | Bodily symptoms in panic | Daily diary |
| | Avoidance | |
| | Safety behaviors | |
| 3 | *In vivo* exposure: | *In vivo* exposures |
| | Defining an anxiety hierarchy | Dizziness interoceptive exercises |
| | | Daily diary |
| 4 | Cognitive restructuring I: | *In vivo* exposures |
| | Negative automatic thoughts | Further interoceptive exposure exercises |
| | Defining anxiety project (training schedule for exposures) | Daily diary |
| 5 | Cognitive restructuring II: | *In vivo* exposures |
| | Reality testing of automatic negative thoughts | Further interoceptive exposure exercises |
| | | Daily diary |
| 6 | Relapse prevention: | Breathing and muscle relaxation exercises |
| | Early warning signs | |
| | Critical life events | |
| | Evaluation of training and aims | |

Throughout the study, participants will receive online technical support from an IT specialist to install the app, access to a personal online coach (a trained psychologist) to answer any questions, reminder messages for homework assignments, and brief homework feedback from the online coach based on a manual written by the first author (LE). All online coaches will receive online training with regard to GET.ON PANIC by the first and second authors (LE and SKSt), and will be supervised by licensed and experienced psychotherapists when offering guidance. The total amount of coaching time per participant will be approximately three hours for the duration of the six-week online training.



**Figure 2 App screenshot of GET.ON PANICAPP.** The app supports in vivo exposures. Participants start with ranking their anxiety provoking situations in a hierarchical order. Furthermore, they are asked to answer questions about their anxiety before and after performing the exposure exercise (for example the level of anxiety, the degree of avoidance and the severity of body symptoms). In addition, they have the ability to take a photo after in vivo exposure exercise is completed. The bar chart in the end offers graphical feedback to the participants regarding the exposure performance.

**Instruments**

For an overview of the instruments at screening, baseline, after treatment, and at the follow-up assessments, see Table 2.

**Screening and diagnostic interview**

The preliminary screening will collect demographic data from participants, including their age, gender, education, therapeutic experience, and medication use, and the PAS will be administered (for a detailed description see the section regarding the primary outcome measure) [34,35]. Item 9 of the BDI-II [37,38] will be used to screen for suicidality. The BDI-II is a 21-item assessment of depressive symptoms that has demonstrated high internal consistency using outpatient samples [37].

The SCID-I [39] will be used to assess the presence of PD, agoraphobia, other anxiety disorders, and current depressive episodes. A trained interviewer will perform the interview via telephone. Previous studies have demonstrated the validity of telephone-based SCID-I interviews [41,42].

**Table 2 Overview of instruments per time of assessment**

| Assessments | Screening | T0 | T1 | T2 | T3 |
|---|---|---|---|---|---|
| Sociodemographic data | x | - | - | - | - |
| Suicidality (Item 9. BDI-II) | x | - | - | - | - |
| Diagnosis (SCID-I, sections for anxiety disorders and current depressive episode | - | x | - | - | - |
| Panic and agoraphobia severity, self-rating (PAS) | x | x | x | x | x |
| Panic and agoraphobia severity, observer-rating (HAM-A) | - | x | x | - | - |
| Agoraphobic cognitions (ACQ) | - | x | x | x | x |
| Body sensations (BSQ) | - | x | x | x | x |
| Agoraphobic avoidance (MI) | - | x | x | x | x |
| Depressive symptoms (CES-D) | - | x | x | x | x |
| Quality of life (EQ-5D, SF-12) | - | x | x | x | x |
| Economic evaluations (TiC-P) | - | x | - | - | x |
| Negative effects on online health trainings | - | - | (x) | (x) | (x) |
| Attitudes towards seeking psychological help | - | - | (x) | - | - |
| User satisfactory | - | - | (x) | - | - |
| Technology acceptance of the app | - | - | (x) | - | - |
| Usability of smartphone app (SUS) | - | - | (x) | - | - |

T0 = Baseline, T1 = 8 weeks, T2 = 3 months, T3 = 6 months.
Assessments: x = intervention and control group, (x) = intervention group only.
ACQ, Agoraphobic cognitions questionnaire; BDI-II, Beck Depression Inventory II; BSQ, Body sensations questionnaire; CES-D, Center for epidemiological studies depression scale; EQ-5D, EuroQol; HAM-A, Hamilton anxiety scale; MI, Mobility inventory; PAS, Panic and agoraphobia scale; SCID-I, Structured clinical interview for DSM-IV Axis I Disorders; SF-12, Short form 12; SUS, System Usability Scale; TiC-P, Trimbos and the Institute of Medical Technology Assessment Cost Questionnaire for Psychiatry.

**Primary outcome measure**

*Panic severity*

The primary outcome will be the severity of panic and agoraphobia symptoms as assessed by the total PAS score [34,35,48]. This questionnaire was originally developed as a self- and observer-rating scale. In this study, we will use the self-rating questionnaire that was adapted into an online version. The PAS consists of 13 items grouped into five subscales, and an extra item regarding unexpected versus expected panic attacks. The five subscales assess the following areas: panic attacks, agoraphobic avoidance, anticipatory anxiety, daily life limitations, and health concerns (for example, the fear of physical harm or the fear of an organic cause). These subscales can be evaluated separately or as a total score that combines all subscales, ranging from 0 to 52 points. A higher score on the PAS indicates more panic symptoms. The psychometric properties of the scale are satisfactory, with a Cronbach's alpha of 0.86 [49]. A score of between 0 and 8 indicates no clinically relevant symptoms, scores of between 9 and 28 indicate moderate symptoms, and a score of 29 or higher indicates a severe level of symptoms [49].

**Secondary measures**

*Depression*

Depressive symptoms will be measured using the Allgemeine Depressions-Skala (ADS) [50], the German adaptation of the Center for Epidemiological Studies Depression Scale (CES-D) [51]. The ADS consists of 20 items that refer to the previous week and are answered using a four-point Likert scale. The total score ranges from 0 to 60. Its internal consistency is $\alpha = 0.89$, and its split-half reliability is $r = 0.91$ [50].

*Quality of life*

Quality of life will be measured using the EuroQol (EQ-5D) [52] and the Short Form 12 (SF-12) [53]. The EQ-5D is a well-established measurement of quality of life that consists of five items assessing mobility, self-care, common activities, pain and/or discomfort, and anxiety and/or depression, as well as a visual analogue scale concerning health status. We will also use the SF-12, which consists of 12 items that assess eight health domains: physical functioning, role limitations, pain, general health perception, vitality, mental health, emotional role, and social functioning. The SF-12 generates two summary scores: physical health and mental health.

**Agoraphobic cognitions**

Agoraphobic cognitions will be measured using the Agoraphobic Cognitions Questionnaire (ACQ) [54,55]. The ACQ consists of 14 items, and its total score ranges from 14 to 70. Craske *et al.* reported that the ACQ has an internal reliability of $\alpha =0.80$ [56].

**Bodily sensations**

The Body Sensation Questionnaire (BSQ) [54,55] is a 17-item self-report questionnaire that measures bodily sensations. The BSQ ranges from 17 to 85 points and has a satisfactory internal reliability of $\alpha =0.87$ [54].

**Agoraphobic avoidance**

The Mobility Inventory (MI) [54,55] measures agoraphobic avoidance. The MI consists of 27 items that address the most important agoraphobic situations. Each item is rated both for when patients are alone and when they are accompanied. These two scales have a summed score ranging from 27 to 135 points, respectively. The internal consistencies are $\alpha =0.94$ (alone) and $\alpha =0.91$ (accompanied) [57].

**Observer rating anxiety symptoms**

In addition, the secondary outcome measures will include the observer-rated HAM-A [43,58] to obtain a more detailed understanding of symptom severity. The HAM-A is a 14-item clinician-reported rating scale with a total score ranging from 0 to 30. Thus, we will use the structured interview guide for the HAM-A (SIGH-A) [59]. The interview has shown satisfactory inter-rater and test-retest reliabilities of Intraclass Correlation Coefficients of respectively 0.99 and 0.89 [59].

**Economic evaluation**

We will use an adaption of the Trimbos/iMTA questionnaire to measure the costs associated with psychiatric illness (TiC-P) [60] with regard to the German healthcare system.

**Diary data**

EMA data will be collected via the mobile application GET.ON PANIC APP [47]. This app contains a diary where clients can record their panic attacks and monitor their progress using daily summaries. With regard to the latter, clients will summarize their general anxiety levels, their degree of avoidance, and their moods each evening. The application also records the type and number of exposure exercises performed by the client.

**Additional measures**

We will also collect data concerning technology acceptance (via a questionnaire based on the technology acceptance model; TAM) [61,62], the usability of the smartphone app GET.ON PANIC APP (via the System Usability Scale; SUS) [63,64], user satisfaction of the online training (a self-designed questionnaire based on the German version of the Client Satisfaction Questionnaire [65,66], and the adverse effects of psychotherapy [67].

**Statistical analyses**

The analyses will be performed based on the Consolidated Standards of Reporting Trials (CONSORT) statement regarding eHealth [68]. The data will be analyzed on an intention-to-treat basis. We will also conduct per protocol and completers-only investigations as secondary analyses.

**Treatment efficacy**

Group differences in the baseline values of the primary outcome will be compared using t-tests to assess whether randomization was successful. Missing data will be addressed following the recommendations of Little and Rubin [69] and Schafer [70]. We will analyze the PAS data at eight weeks post-treatment using between-group analyses of covariance with regard to the individual baseline PAS scores, adjusted for sex, age, and socioeconomic status. We will use Cohen's d to measure the between-group effect size. Cohen's d will be calculated as the difference between the mean post-test scores of the intervention group and the control group divided by the pooled standard deviation [71]. All other secondary outcomes will be analyzed in a similar manner.

We will also conduct clinical significance change analyses as described by Jacobson and Truax [72]. In the first step, we will test whether the changes from pre-test to post-test are statistically reliable and build a reliable change index (RCI). In the second step, we will calculate clinical significance. Based on the RCI, the participants who display a reliable positive change, no change, or a reliable deteriorated change will be classified as responders, non-responders, or deteriorated, respectively [72]. We will use mixed-model regressions to examine the long-term effect on the primary outcome after three and six months.

**Economic analyses**

We will conduct an economic evaluation by performing a cost-effectiveness analysis (CEA) and a cost-utility analysis (CUA) from a societal perspective. The clinical outcome of the

CEA will be the severity of panic symptoms as assessed by the PAS. Quality-adjusted life years (QALYs) will be calculated for the CUA. A non-parametric bootstrapping method with 95% confidence intervals will be used to assess the differences between the intervention and control groups. The intervention and waitlist control groups will be compared in terms of incremental costs and incremental effects. Thus, we will calculate the incremental cost-effectiveness ratio (ICER). Bootstrapping via 5,000 iterations will be used to quantify the uncertainty in the ratios and to test the robustness of the ICER. The results will be displayed on a cost-effectiveness plane and via a cost-effective acceptability curve. A multi-way sensitivity analysis will be conducted to test the robustness of the base-case findings. For instance, these analyses will integrate data based on the EMA to reduce the retrospective bias of self-reported panic symptom severity.

## Discussion

Given the availability and the daily use of smartphones, mobile-based health interventions have become increasingly popular [73-78]. Evidence for the efficacy of these studies comes from attempts to promote physical activity [79], cope with schizophrenia [25], and overcome child anxiety [80]. Despite the obvious advantages of integrating mobile components into online-based treatments (for example, mobile components can be used for EMA, supporting exposure exercises away from home, and EMI), no data are available regarding the efficacy of such an intervention for PD. Thus, we developed the hybrid online training GET.ON PANIC based on CBT, and we will test the efficacy and cost-effectiveness of this online training among people with clinical or subclinical PD with or without agoraphobia at post-assessment, as well as at three- and six-month follow-ups, compared with a waitlist control group who will receive the online training after the last assessment, but who will have free access to the usual treatments.

This study has several limitations. First, the absence of an active control group does not allow us to clarify the mechanisms responsible for changes in treatment. However, because this study is one of the first to test the efficacy of hybrid online training for PD, evaluating the efficacy of the intervention is an important research question in and of itself. If the present study provides evidence regarding the efficacy of GET.ON PANIC, then future research should detect the mechanisms that drive the change within the intervention. Such research should also include dismantling studies that compare online-based interventions with or without a mobile component to explain the additional benefits of including a mobile

component. Second, using a waitlist control group design does not enable a comparison between newly developed hybrid online training and the current gold standard (face-to-face CBT to treat people with PD and agoraphobia). Future studies should compare hybrid online training with the gold standard. Finally, this study is not designed to test the long-term efficacy of GET.ON PANIC. With an assessment time of six months, we will only be able to make conclusions over a relatively short period of time. A 12-month follow-up assessment is desirable.

## Trial status

The study is currently ongoing. Recruitment began in August 2013 and will conclude in October 2014.

## Abbreviations

ACQ: Agoraphobic cognitions questionnaire; BDI-II: Beck Depression Inventory II; BSQ: Body sensations questionnaire; CBT: Cognitive behavioral therapy; CEA: Cost-effectiveness analysis; CES-D: Center for epidemiological studies depression scale; CONSORT: Consolidated standards of reporting trials; CUA: Cost-utility analysis; DRKS: German Clinical Trial Register; EMA: Ecological momentary assessment; EMGO: Institute for Health and Care Research; EMI: Ecologically momentary intervention; EQ-5D: EuroQol; HAM-A: Hamilton anxiety scale; ICER: Incremental cost-effectiveness ratio; INEP: Adverse effects of psychotherapy; MI: Mobility inventory; PAS: Panic and agoraphobia scale; PD: Panic disorder; QALYs: Quality-adjusted life years; RCI: Reliable change index; RCT: Randomized controlled trial; SCID-I: Structured clinical interview for DSM-IV Axis I Disorders; SF-12: Short form 12; SUS: System Usability Scale; TAM: Technology acceptance model; TiC-P: Trimbos and the Institute of Medical Technology Assessment Cost Questionnaire for Psychiatry; VU: Vrije Universiteit.

## Competing interests

The authors declare that they have no competing interests.

## Authors' contributions

All authors contributed to the study design. LE, DL, DE, WvB and MB developed the hybrid online training for treating people with PD with or without agoraphobia (GET.ON PANIC).

SKSt developed the app (GET.ON PANIC APP). BF supervised the technical aspects of the intervention. LE drafted the manuscript. HJ, DL, HR and MB revised the manuscript. All authors read and approved the final manuscript.

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# Kapitel 4: Wirksamkeitsstudie GET.ON Panik

## Treating panic on the go: Results of a randomized controlled trial evaluating a hybrid online training for panic disorder and agoraphobia

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## Abstract

### Objective

Previous studies provide evidence for the effectiveness of web-based interventions for panic disorder with and without agoraphobia (PD). Smartphone-based technologies hold significant potential for further enhancing accessibility and efficacy of such interventions. The aim of the present randomized controlled trial (RCT) was to evaluate the efficacy of a hybrid online training for adults suffering from PD symptoms.

### Method

Participants (N = 92) with total scores in the Panic- and Agoraphobia Scale (PAS) ranging from 9 to 28 were recruited from the general population and allocated either to a hybrid intervention (GET.ON Panic) or to a wait-list control group (WLC). The primary outcome was the reduction of panic symptoms as assessed with the PAS.

### Results

ANCOVA-based intention-to-treat analyses revealed a significantly stronger decrease in panic symptoms ($F = 9.77$, $p < 0.01$; $d = 0.66$; 95% CI 0.24 - 1.08) in the intervention group compared with the WLC group at post-treatment. Comparisons between groups at the follow-up measures at 3 and 6 months yielded even stronger effects (3M-FU: $F = 17.40$, $p < 0.001$; $d = 0.89$; 95% CI 0.46 - 1.31; 6M-FU: $F = 14.63$, $p < 0.001$; $d = 0.81$; 95% CI 0.38 - 1.24).

### Conclusions

Hybrid online trainings may help reduce symptoms of PD and hence play an important part in improving health care for patients suffering from this debilitating disorder.

### What is the public health significance of this article?

The present study provides evidence that a hybrid internet training can help reduce symptoms of panic disorder. As internet-based interventions are often easier to disseminate than traditional face-to-face treatments, these findings have important implications for endeavors to facilitate access to evidence-based treatments.

### Keywords

panic disorder; treatment; internet; mobile; randomized controlled trial

## Background

With a 12-month prevalence of 1.8% among adults, panic disorder (PD) is one of the most common anxiety disorders (Wittchen, Heinig, & Beesdo-Baum, 2014; Wittchen et al., 2011). Sub-threshold cases, defined as significant panic symptoms that fail to meet full criteria, have been estimated to be just as prevalent (Batelaan, De Graaf, van Balkom, Vollebergh, & Beekman, 2007; Kessler et al., 2006) and have been shown to predict the development of full PD as well as other mental disorders such as generalized anxiety disorder or major depression (Kinley, Walker, Enns, & Sareen, 2011). Effective treatments for PD and associated agoraphobic symptoms include pharmacotherapy and cognitive behavior therapy (CBT) (Bandelow, Lichte, Rudolf, Wiltink, & Beutel, 2015; National Institute for Health and Care Excellence [NICE], 2011; Sánchez-Meca, Rosa-Alcázar, Marín-Martínez, & Gómez-Conesa, 2010; van Balkom et al., 1997). Unfortunately, many individuals still lack access to evidence-based treatments because of limited availability of clinicians or fear of stigmatization (Andrews, Issakidis, & Carter, 2001; Coles & Coleman, 2010; Mojtabai et al., 2011).

Technology-based psychological interventions making use of the internet provide low-threshold access to evidence-based mental health care. Recent outcome studies (e. g. Allen et al., 2016; Berger et al., 2017; Ciuca, Berger, Crişan, & Miclea, 2018), meta-analyses and reviews (Andersson, 2012; Andersson, Cuijpers, Carlbring, Riper, & Hedman, 2014; Andrews, Cuijpers, Craske, McEvoy, & Titov, 2010; Andrews et al., 2018; Cuijpers, Donker, van Straten, Li, & Andersson, 2010; Haug, Nordgreen, Öst, & Havik, 2012; Mewton, Smith, Rossouw, & Andrews, 2014; Olthuis, Watt, Bailey, Hayden, & Stewart, 2015; Spek et al., 2007) provide ample evidence that internet-based interventions based on CBT-principles (iCBT) are effective in treating PD.

Because of its ability to bridge distances between patients and therapist, good cost-efficacy and low-threshold iCBT has great potential to facilitate access to evidence-based interventions (Andrews et al., 2010; Hedman et al., 2013). However, the current dominance of desktop-based iCBT in research and health services neglects the dramatic shift in user preferences towards the use of smartphones (International Telecommunication Union [ITU], 2017). Moreover, smartphones accompany their users wherever they go and thereby provide an excellent opportunity for ecological momentary assessment of relevant health information (Alpers, 2009; Helbig, Lang, Swendsen, Hoyer, & Wittchen, 2009; Moskowitz,

Russell, Sadikaj, & Sutton, 2009; Myin-Germeys et al., 2009; Trull & Ebner-Priemer, 2009). Furthermore smartphones allow the use of ecological momentary interventions being delivered in real world and real time – ideally just at the very moment the intervention is needed (Heron & Smyth, 2010). Considering the rapid growth and potential of mobile technology, surprisingly little research has been conducted to clarify the benefits of utilizing smartphones as stand-alone or add-on interventions (e. g. Wang et al., 2018). Available data often comes from studies criticized for poor quality interventions (van Singer, Chatton, & Khazaal, 2015) and many interventions currently available have not been evaluated at all (Donker et al., 2013; Marcolino et al., 2018; Sucala et al., 2017).

The few currently available studies provide preliminary evidence for the efficacy of smartphone-based interventions for symptoms of anxiety disorders. For example, in a meta-analysis on efficacy of transdiagnostic eHealth interventions that integrated mobile technologies, Firth and colleagues (2017) showed that such interventions can significantly reduce overall anxiety (Hedge's g = 0.45). A recent study by Christoforou, Sáez Fonseca, & Tsakanikos (2017) evaluated the efficacy of an app for agoraphobic symptoms in comparison to a stress reduction app. While there was a significant pre-to-posttest effect for the interventions (Panic and Agoraphobia Scale [PAS] difference -5.97, 95% CI -8.49 – -3.44) there were no significant differences between the interventions.

Despite these promising findings, it is important to acknowledge that mobile applications also show some disadvantages with regard to usability issues. For example, elaborate writing tasks, a typical component of iCBT interventions, are difficult to complete on a small screen with a smartphone touchpad. Moreover, mobile phones are typically used for short time intervals and often while performing other tasks. This is problematic as working towards health promoting changes often requires more sustained and focused efforts (Middleton, Anton, & Perri, 2013; Min, Lee, & Lee, 2013). Therefore, it can be argued that hybrid interventions which combine the advantages of both desktop and mobile technology should be superior to exclusively desktop or mobile-based approaches. In hybrid interventions the mobile component can be used to monitor symptoms and cue exercises in the patient's natural environment whereas the desktop component provides text- and video-based psychoeducation and facilitates elaborated writing tasks.

In spite of the obvious advantages of hybrid interventions literature on their efficacy is still scarce. In a transdiagnostic approach Proudfoot and colleagues (2013) showed that the

delivery of CBT using a combination of mobile application and desktop-based technology (myCompass) was effective in reducing symptoms of anxiety disorders (Cohen's d = 0.47) compared to a wait-list control condition. Furthermore, a study evaluating the combination of Acceptance and Commitment Therapy (ACT) and a smartphone application for participants suffering from PD or Social Phobia (SP), Ivanova and colleagues (2016) found no significant effect on panic symptom severity reduction. At this point, no study has been published on the efficacy of hybrid iCBT intervention for PD. To fill this gap in the literature, the present study aimed to evaluate the efficacy of a newly developed hybrid iCBT training for individuals suffering from symptoms of PD.

## Methods

### Study Design

To evaluate the efficacy of a hybrid online training for PD (with and without agoraphobia) we conducted a prospective, 2-arm, randomized trial, in which N = 92 participants suffering from significant symptoms of PD were randomly allocated either to the GET.ON Panic intervention group or to the WLC group. For randomization we used the automated computer program DatInf RandList Version 1.2 (DatInf GmbH, Tübingen, Germany). The allocation was stratified for clinical or subclinical symptomatology, as well as the presence or absence of agoraphobia in the order of incoming informed consents. In order to include equal numbers of participants in each group we used block randomization (n = 2 per block). Staff conducting diagnostic interviews and observer ratings were blinded with regard to participants' randomization status. Ethical approval for this study was obtained from the Ethical Committee of the University of Marburg (registration number: 2013-23 K). The study was pre-registered with the German Clinical Trial Register (registration number: DRKS00005223). The study protocol was submitted to publication prior to start of randomization (Ebenfeld et al., 2014).

**Participants and Recruitment**

The study participants were recruited between August 2013 and October 2014 from the general population. Announcements in newspapers, support groups and social media as Facebook guided interested individuals to the online health center website of our research group (https://geton-training.de) where they could apply online for study participation. Applicants were asked to complete an online-questionnaire assessing the following inclusion criteria: (i) experiencing mild to moderate panic symptoms as assessed by the PAS (score range: 9 to 28) (Bandelow, 1995, 1997); (ii) being 18 years or older; (iii) having panic as the primary concern for seeking help; and (iv) having internet and smartphone access with minimum system requirements of iPhone™ 3GS (iOS 6, iOS 7) or a comparable Android device (Android 2.3 or newer).

The exclusion criteria were: (i) receiving current psychological help for anxiety problems or being on a wait-list for psychotherapy; (ii) having physical health problems assessed via self-report that prevents participants from engaging in self-exposure, as recommended by the German guideline for treating people with PD and agoraphobia (Schneider & Margraf, 2017); (iii) currently having posttraumatic stress disorder or psychotic or dissociative disorders assessed via self-report and clinical interview; and (iv) having current suicidality, as assessed by a score above 1 on item 9 of the Beck Depression Inventory II (BDI-II; Beck, Steer, & Brown, 1996; Hautzinger, Keller, & Kühner, 2006) and question A9 of the Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I; Wittchen, Zaudig, & Fydrich, 1997). In the event that potential participants were excluded because of suicidal ideation or intention, they were given information about further help according to an established suicide protocol. All participants excluded were contacted via email and provided with information regarding where they can obtain appropriate help.

**Treatment**

Participants in the treatment condition received the GET.ON Panic treatment which is a hybrid (i.e., desktop- as well as smartphone-based ), iCBT-based, self-help intervention for treating symptoms of PD (Ebenfeld et al., 2014). Participants were advised to log on to the training platform on a weekly basis and consecutively work through the following sessions: (i) psychoeducation, (ii) interoceptive exposure, (iii) in-vivo exposure, (iv) cognitive restructuring – introduction, (v) cognitive restructuring – extension, and (vi), relapse prevention. In addition, participants were instructed in the complementary use of the

GET.ON Panic App (Kleine Stegemann, Ebenfeld, Lehr, Berking, & Funk, 2013). The app supported participants in (i) completing their homework assignments (e. g., keeping an anxiety diary), (ii) planning, conducting and evaluating interoceptive and in-vivo exposure tasks, and (iii) performing relaxation exercises. For an overview of training see Table 1.

**Table 3 Overview of sessions**

| Week | Content and homework | |
|------|----------------------|---|
| | **Browser:** | **Mobile:** |
| 1 | Psychoeducation:<br>Information about panic<br>Defining goas of training<br>Setting up a reward list | Daily diary<br>Registration of current panic event (event-based)<br>Daily summary of panic, avoidance, and mood |
| 2 | Interoceptive exposure:<br>Bodily symptoms in panic<br>Avoidance<br>Safety behaviors | Respiratory interoceptive exposure exercises<br>Daily diary |
| 3 | *In vivo* exposure:<br>Defining an anxiety hierarchy | *In vivo* exposures<br>Dizziness interoceptive exercises<br>Daily diary |
| 4 | Cognitive restructuring I:<br>Negative automatic thoughts<br>Defining anxiety project (training schedule for exposures) | *In vivo* exposures<br>Further interoceptive exposure exercises<br>Daily diary |
| 5 | Cognitive restructuring II:<br>Reality testing of automatic negative thoughts | *In vivo* exposures<br>Further interoceptive exposure exercises<br>Daily diary |
| 6 | Relapse prevention:<br>Early warning signs<br>Critical life events<br>Evaluation of training and aims | Breathing and muscle relaxation exercises |

After every session, participants received written feedback from a trained coach based on a coaching manual developed by members of our research group to ensure a standardized procedure of coaching (Ebenfeld, Kleine Stegemann, Wiencke, & Lehr, unpublished work). The manual is available upon request. The guidance was rather focused on increasing motivation and adherence throughout the training progress than providing individual therapeutic advice. Coaches also sent reminders via a secure messaging system within the training platform, if participants did not log on for one week. All coaches had a degree in psychology and were supervised by a licensed clinical psychologist.

**Outcome Measures**

*Panic symptom severity, self-rating*

The primary outcome was the severity of panic and agoraphobia symptoms as assessed with the self-rating by the Panic and Agoraphobia Scale (German Version: Panik- und Agoraphobieskala) (PAS; Bandelow, 1995, 1997; Bandelow et al., 2000; Bandelow, Hajak, Holzrichter, Kunert, & Rüther, 1995). This scale consists of 13 items separated into the subscales panic attacks, agoraphobic avoidance, anticipatory anxiety, daily life limitations, and health concerns. For each item, participants rate the frequency of panic symptoms during the past week on a 5-point scale. Thus, the total score ranges from 0 to 52, with scores ranging from 0 to indicating "no clinically relevant symptoms", scores ranging between 9 and 28 indicating "moderate symptoms", and a score of 29 and above indicating a "severe level of symptoms". Previous studies provide evidence for the efficacy of the measures e. g., Cronbach's alpha $a = 0.86$, (Bandelow, 1997) or $a = 0.70 - 0.94$ (Wölk, Sütterlin, Koch, Vögele, & Schulz, 2014). In the present study, Cronbach's $a$ for the total score is 0.89.

*Observer-rated anxiety symptoms*

The Hamilton-Anxiety-Scale (HAM-A; Hamilton, 1959; Shear et al., 2001; Weyer, 2005) was used as a complement for the self-administered anxiety scales. The scale contains 14 items with a total score ranging from 0 to 30. Previous studies showed excellent inter-rater and test-retest reliabilities of Intraclass Correlations Coefficients (ICC) of $0.89 - 0.99$ (Shear et al., 2001). For examining inter-rater reliability in this trial, we audio-taped all observer ratings. Around one tenth (equivalent to 30 interviews) of these audios were rated by experienced, blinded second raters. The inter-rater reliability was excellent with $ICC = 0.99$.

**Agoraphobic cognitions**

The Agoraphobic Cognitions Questionnaire (ACQ) is a 14-item self-report questionnaire that measures agoraphobic cognitions. The total sum score of the ACQ ranges from 1 to 5. The ACQ has an internal reliability of Cronbach's $a = 0.80$ (Chambless, Caputo, Bright, & Gallagher, 1984; Craske, Rachman, & Tallman, 1986; Ehlers & Margraf, 2001). In this trial we found a Cronbach's $a = 0.84$.

**Body sensations**

Bodily sensations were measured using the Body Sensations Questionnaire (BSQ), a self-rating questionnaire ranging from total sum score of 1 to 5 points. It has a good internal reliability of Cronbach's $a = 0.87$ (Chambless et al., 1984; Ehlers & Margraf, 2001). In the current trial, Cronbach's $a$ was 0.86.

**Agoraphobic avoidance**

The Mobility Inventory (MI) is a questionnaire that measures agoraphobic avoidance. Participants were asked to rate common agoraphobic situations with regard to avoidance of them. Each item is rated twice; once for dealing with the situation alone and once when accompanied. The total sum score ranges from 1 to 5 points, respectively. The internal consistencies reported in previous studies, were very good with Cronbach's $a$ 0.91 (accompanied by significant others) and 0.94 (alone) (Chambless, Caputo, Jasin, Gracely, & Williams, 1985; Chambless et al., 1984; Ehlers & Margraf, 2001). In the present study, Cronbach's $a$s of the MI were 0.93 (accompanied) and 0.95 (alone).

**Depressive symptoms**

We used the German adaption (ADS) of the Center for Epidemiological Studies Depression Scale (CES-D) to assess depressive symptom severity. The CES-D measures 20 symptoms of depression in the previous week. The total score ranges from 0 to 60. The internal consistency has shown to be good (Cronbach's $a = 0.89$) (Hautzinger & Bailer, 1993; Radloff, 1977). In the present study, Cronbach's $a$ was 0.87.

**Diagnostic status**

Presence of PD, any other anxiety disorder, or a current depressive episode (MDE) was assessed with a telephone version of the Structured Clinical Interview for DSM-IV (SCID-IV) at 6-month follow-up assessment covering the period of the last 3 months by trained

interviewers. Previous studies have shown excellent test-retest reliability between the two different formats, the telephone version and the face-to-face version of the diagnostic interview (Cohen's Kappa $\kappa = 0.84$) (Crippa et al., 2008; Irvine, Drew, & Sainsbury, 2012; Rohde, Lewinsohn, & Seeley, 1997). To determine the interrater reliability of the diagnostic interviews, we used Kappa statistics. In a previous study a moderate interrater reliability Cohen's Kappa $\kappa = 0.67$ has been found (Lobbestael, Leurgans, & Arntz, 2011). In the current trial, all interviews were audio-taped with 10 % of these interviews were rated by an experienced, blinded second rater. Agreement between the two raters was moderate with Cohen's Kappa $\kappa = 0.51$.

### Quality of life

Quality of life was measured with the 12-Item Short Form Health Survey assessing eight health domains: physical functioning, role limitations, pain, general health perception, vitality, mental health, emotional role, and social functioning. The SF-12 provides two summary scores for physical and mental health respectively (SF-12; Gandek et al., 1998; Ware, Kosinski, & Keller, 1996). In the present trial Cronbach's $a$ was 0.79.

### User satisfaction

We assessed user satisfaction with the Client Satisfaction Questionnaire adapted to Internet-based interventions (CSQ-I; Boß et al., 2016) which is based on the German version of the Client Satisfaction Questionnaire (CSQ-8; Attkisson & Zwick, 1982; Schmidt, Lamprecht, & Wittmann, 1989). Statements such as "I would recommend this training to a friend, if he or she was in need of similar help." are rated on a 4-point Likert scale (ranging from 1 = "Does not apply to me" to 4 = "Does totally apply to me."). The questionnaire contains eight items with a sum score ranging from 8 to 32. Psychometric properties were excellent with McDonald omega of $\sigma = 0.93$ and $\sigma = 0.95$ (Boß et al., 2016). In the current trial, McDonald omega was $\sigma = 0.97$.

### App Usage

The mobile application contains a diary for recording and monitoring panic-related symptoms as occurred panic events, degree of avoidance behavior and general anxiety and mood level on a visual analogue scale (0 to 10). Furthermore, the application records type and number of exposure exercise as performed by the participant. In addition, we used the System Usability Scale (SUS) at T2 to assess the usability of the GET.ON Panic app (Bangor,

Kortum, & Miller, 2009; Brooke, 1996). The sum-score ranges from 0 to 100; with a higher score indicating better usability.

**Assessment Schedule**

Participants completed a sociodemographic questionnaire, the PAS and the Suicidality item of BDI-II at screening (T0); at baseline (T1) we assessed the PAS, the SCID-I, the HAM-A, the ACQ, the BSQ, the MI, the CES-D and the SF-12; at post-assessment (T2) we assessed the PAS, the HAM-A, the ACQ, the BSQ, the MI, the CES-D, the SF-12, the CSQ-I (only intervention group) and the SUS (only intervention group); at 3-month follow-up (T3) we assessed the PAS, the ACQ, the BSQ, the MI, the CES-D and the SF-12 and at 6-month follow-up (T4) we assessed the PAS, the SCID-I, the HAM-A, the ACQ, the BSQ, the MI, the CES-D and the SF-12. Diary data were measured continuously during the training period and beyond.

**Statistical Analyses**

To assess treatment efficacy, the GET.ON Panic group was compared with the WLC group on all outcome measures (T2, T3 and T4) using univariate analyses of covariance (ANCOVA) with the baseline scores as covariates. Based on a previous meta-analysis (Haug et al., 2012) we powered the study to detect an effect size of Cohen's $d = 0.6$ (1-$\beta$ of 80%, $a = 0.05$) with intention-to-treat (ITT) as our primary level of analyses. As a measure of effect size we calculated Cohen's $d$ (Cohen, 1988). To account for the covariance, we calculated Cohen's $d$ over partial eta squared ($\eta^2$). To assess a clinically reliable change of panic severity (response) on an individual level we calculated the Reliable Change Index (RCI) as proposed by Jacobson and Truax (1991), coded participants as responders or deteriorators if their score on the PAS differed 10.68 points on the PAS and performed a Pearson $Chi^2$ test to compare the reliable change of the GET.ON Panic group with the WLC. Corresponding to the RCI, we calculated a Numbers Needed to Treat (NNT) score indicating how many participants must take part in order for GET.ON Panic to achieve one clinically relevant improvement. To assess remission rates, we calculated the percentage of people who had a diagnostic status of PD according to the SCID-I interview at baseline (T0) and at 6-month follow-up (T4) and performed a Pearson $Chi^2$ test to compare the diagnostic status of the GET.ON Panic group with the WLC covering a period of the last 3 months.

Missing data at post, 3-month follow-up and 6-month follow-up assessments were imputed using a Markov Chain Monte Carlo multivariate imputation algorithm (SPSS 23) with

hundred estimations per missing value and all available data on outcomes as well as age and gender as predictors (Schafer & Graham, 2002).

## Results

### Enrollment

Figure 1 summarizes the flow of participants throughout the study. Over a period of 14 months a total of 235 individuals completed the screening questionnaire. Of these, 117 did not meet the inclusion criteria or matched one or more exclusion criteria. The most frequent reasons for exclusion were too severe panic symptom severity (n = 53), current psychotherapy (n = 34) or physical contra-indications (n = 23). The remaining 118 candidates were eligible for participating in the clinical interview. Of those, 19 did not send back their informed consent. After this interview another six candidates were excluded because they did not have panic symptoms as their primary reason for seeking help. All individuals excluded were provided with information about applicable health care system services. The remaining 92 participants were randomly assigned to the hybrid online training GET.ON Panic or the WLC condition.
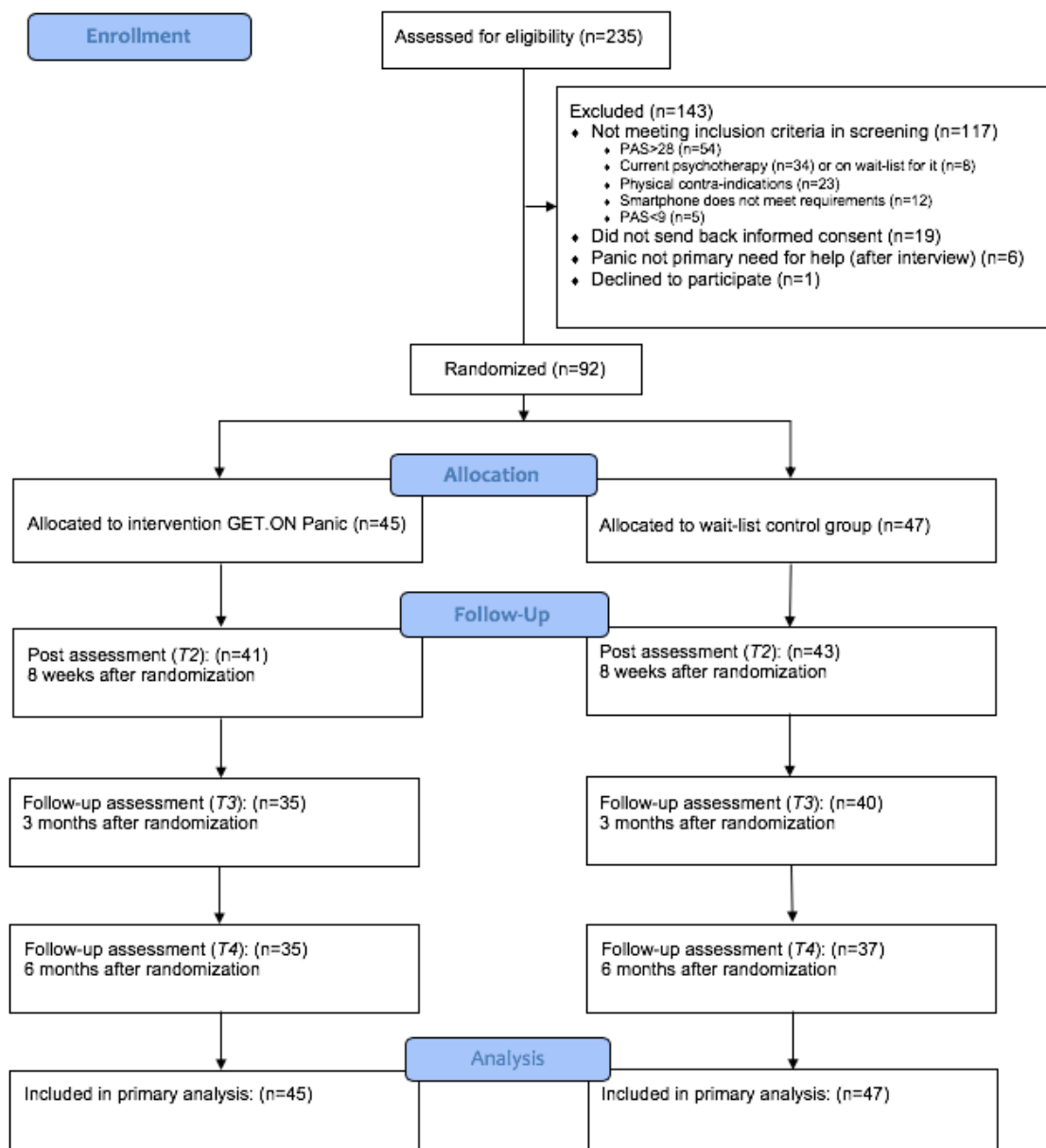
*Figure 1. Study flow.*

## Baseline Characteristics

Characteristics of the final sample are summarized in Table 2. The majority of participants was female (n = 51; 55%), white (n = 76; 83%), on average 38 years old (SD = 10.42), highly educated (n = 60; 65%), married or in a relationship (n = 82; 89%) and currently working (n = 51; 55%). Based on the SCID-interview, the most common diagnosis was PD with agoraphobia (n = 78; 83%). A significant number of patients (n = 12; 13%) met criteria for PD without agoraphobia. Of all participants, 26% met the criteria of at least one additional

anxiety disorder in addition to PD. A small percentage (2%) suffered from a current Major Depressive Episode as comorbid condition. Most participants (63%) reported that they had previously been in psychotherapeutic treatment.

Table 2

*Characteristics of Study Sample (N=92) Allocated to Online Training GET.ON Panic (n = 45) and Wait-list Control Group (WLC) (n = 47) at Baseline.*

|  | All | GET.ON Panic | WLC |
|---|---|---|---|
| Sociodemographic characteristics |  |  |  |
|    Age in years, M (SD) | 38.36 (10.42) | 39.33 (10.83) | 37.43 (10.03) |
|    Gender, n (%) female | 51 (55.4) | 27 (60.0) | 24 (51.1) |
|    Ethnicity, n (%) |  |  |  |
|       White | 76 (82.6) | 38 (84.4) | 38 (80.9) |
|       Asian | 1 (1.1) |  | 1 (2.1) |
|       NA | 15 (16.3) | 7 (15.6) | 8 (17.0) |
|    Marital status, n (%) |  |  |  |
|       Never married | 37 (40.2) | 16 (35.6) | 21 (44.7) |
|       Married or in a partnership | 48 (52.2) | 27 (60.0) | 21 (44.7) |
|       Divorced or widowed | 7 (7.6) | 2 (4.4) | 5 (10.6) |
|    Educational level, n (%) |  |  |  |
|       Low (primary) | 7 (7.6) | 3 (6.7) | 4 (8.5) |
|       Middle (secondary) | 25 (27.2) | 11 (24.4) | 14 (29.8) |
|       High (A-level or higher) | 60 (65.2) | 31 (68.9) | 29 (61.7) |
|    Employment, n (%) |  |  |  |
|       Full-time | 52 (56.5) | 27 (60.0) | 25 (53.2) |
|       Part-time | 30 (32.6) | 15 (33.3) | 15 (31.9) |
|       Nonworking | 6 (6.5) | 3 (6.7) | 3 (6.4) |
|       Unemployed | 1 (1.1) |  | 1 (2.1) |
|       On sick leave | 3 (3.3) |  | 3 (6.4) |
| Clinical characteristics |  |  |  |
|    Severity of panic symptoms (PAS), M (SD) | 18.82 (6.03) | 18.18 (6.54) | 19.43 (5.49) |
|    Primary diagnosis, n (%) |  |  |  |
|       Panic Disorder with Agoraphobia | 78 (84.8) | 39 (86.7) | 39 (83) |
|       Panic Disorder without Agoraphobia | 12 (13) | 5 (11.1) | 7 (14.9) |
|    Subclinical symptoms of PS/A or PS | 2 (2.2) | 1 (2.2) | 1 (2.1) |
|    Comorbidity (one or more), n (%) | 24 (26.1) | 13 (28.9) | 11 (23.4) |
|       Depression (MDE) | 2 (2.2) |  | 2 (4.3) |
|       Social Anxiety Disorder | 3 (3.3) | 2 (4.4) | 1 (2.1) |
|       Specific Phobia | 14 (15.2) | 9 (20) | 5 (10.6) |
|       Obsessive Compulsive Disorder | 1 (1.1) |  | 1 (2.1) |
|       Generalized Anxiety Disorder | 4 (4.3) | 2 (4.4) | 2 (4.3) |
|    Former experience, n (%) |  |  |  |
|       Psychotherapy | 58 (63) | 29 (64.4) | 29 (61.7) |
|          For anxiety symptoms | 50 (54.3) | 23 (51.1) | 27 (57.4) |
|       Mental training | 23 (25) | 14 (31.1) | 9 (19.1) |
|    Use of anxiolytic medication, n (%) | 22 (23.9) | 12 (26.7) | 10 (21.3) |

*Note.* NA = no answer; PAS = Panic and Agoraphobia Scale; PS/A = Panic disorder with Agoraphobia; PS = Panic disorder without Agoraphobia; MDE = Major Depressive Episode

**Study Dropout and Compliance in Treatment**

Baseline data was available for all participants. As indicated in Figure 1, the attrition rate was 8.7% at post-assessment (n = 4 in the IG and n = 4 in the WLC), 18.5% at 3-month follow-up (n = 10 in the IG and n = 5 in the WLC) and 21.7% at 6-month follow-up (n = 10 in the IG and n = 8 in the WLC).

On average, the number of completed sessions in the GET.ON Panic group was 5.11 ($SD$ = 1.67). Out of the 45 participants, 33 (73.33%) completed all six sessions, 2 (4.44%) participants completed only session 1, 5 (11%) participants dropped out after session 2, 3 (6.67%) participants were lost after session 3, 1 (2.22%) participant stopped the training after completing session 4, and 1 (2.22%) participant after session 5. In total, 12 participants did not finish the training. Reasons for intervention drop-out were mentioned for four of them: lack of time, lack of motivation, lack of personal contact with the therapist/eCoach, or surgery that interfered with completing the intervention. The other 8 participants were also study dropouts and no reasons for stopping the intervention were known because they did not complete the post assessment.

**Severity of Panic Symptoms**

Preliminary analyses indicated that all necessary conditions for the intended statistical analyses were met. As shown in Tables 3 and 4, there was a greater decrease of self-reported PD symptom severity in the intervention condition when compared with the WLC condition. With regard to the primary outcome, participants in the GET.ON Panic condition reported significantly lower (baseline-controlled) panic symptom severity at post-treatment than the WLC group ($F$ = 9.77, $p < 0.005$, partial $\eta^2$ = 0.10, $d$ = 0.66, 95% CI 0.24 - 1.08). This effect becomes even stronger ($F$ = 17.40, $p < 0.001$, partial $\eta^2$ = 0.16, $d$ = 0.89, 95% CI 0.46 - 1.31) at 3-month follow-up and remains significant ($F$ = 14.63, $p < 0.001$, partial $\eta^2$ = 0.14, $d$ = 0.81, 95% CI 0.38 - 1.24) at long-term 6-month follow-up. The effect sizes were medium to large.

With regard to observer-based ratings, the ANCOVA showed a significant difference of anxiety symptoms between groups as measured by the HAM-A at post-measurement ($F$ = 3.97, $p < 0.05$, partial $\eta^2$ = 0.04, $d$ = 0.42, 95% CI 0.01 − 0.84) and at 6-month follow-up ($F$ = 4.86, $p < 0.05$, partial $\eta^2$ = 0.05, $d$ = 0.47, 95% CI 0.05 − 0.88) with small-to-medium effect sizes. Further analyses indicated that findings did not significantly change when the analyses were based on the study completer instead of the ITT sample.

Table 3

*Means and Standard Deviations of all outcome variables at baseline, post-treatment, at 3-month and 6-month follow-up (intention-to-treat, N = 92).*

| Outcome | T1 | | | | T2 | | | | T3 | | | | T4 | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | GET.ON Panic | | WLC | | GET.ON Panic | | WLC | | GET.ON Panic | | WLC | | GET.ON Panic | | WLC | |
| | Mean | SD | Mean | SD | Mean | SD | Mean | SD | Mean | SD | Mean | SD | Mean | SD | Mean | SD |
| Panic and agoraphobia severity, self-rating (PAS) | 18.18 | 6.54 | 19.43 | 5.49 | 11.97 | 6.66 | 17.20 | 8.58 | 9.99 | 6.79 | 16.02 | 6.66 | 8.79 | 0.84 | 14.01 | 6.93 |
| Anxiety symptoms, observer-rating (HAM-A) | 15.67 | 8.58 | 16.09 | 7.08 | 12.82 | 6.48 | 15.43 | 7.88 | NA | NA | NA | NA | 10.06 | 6.92 | 12.96 | 7.41 |
| Agoraphobic cognitions (ACQ) | 1.88 | 0.42 | 1.99 | 0.53 | 1.66 | 0.43 | 1.93 | 0.66 | 1.61 | 0.53 | 1.94 | 0.59 | 1.63 | 0.50 | 1.89 | 0.53 |
| Body sensations (BSQ) | 2.44 | 0.61 | 2.47 | 0.51 | 2.16 | 0.60 | 2.40 | 0.66 | 1.94 | 0.55 | 2.34 | 0.68 | 1.92 | 0.41 | 2.23 | 0.66 |
| Agoraphobic avoidance (MI), accompanied | 1.53 | 0.59 | 1.64 | 0.61 | 1.47 | 0.53 | 1.58 | 0.61 | 1.43 | 0.56 | 1.59 | 0.61 | 1.37 | 0.47 | 1.54 | 0.59 |
| Agoraphobic avoidance (MI), alone | 1.92 | 0.71 | 2.06 | 0.85 | 1.75 | 0.68 | 2.03 | 0.90 | 1.70 | 0.65 | 1.95 | 0.84 | 1.55 | 0.54 | 1.93 | 0.88 |
| Depressive symptoms (CES-D) | 17.82 | 7.42 | 19.43 | 8.58 | 15.20 | 8.08 | 17.25 | 7.84 | 14.36 | 8.26 | 16.01 | 8.62 | 10.06 | 6.92 | 12.96 | 7.41 |
| Quality of life (SF-12) physical health | 51.30 | 6.41 | 51.49 | 6.82 | 50.24 | 6.91 | 50.48 | 6.62 | 51.53 | 4.97 | 52.64 | 5.51 | 51.60 | 6.15 | 52.29 | 5.85 |
| Quality of life (SF-12), mental health | 34.03 | 9.47 | 35.61 | 10.48 | 40.63 | 8.92 | 39.76 | 10.55 | 42.37 | 9.14 | 40.57 | 11.47 | 44.54 | 8.86 | 39.94 | 11.82 |

*Note.* WLC = Wait-list control; NA = Not available

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Table 4

*Differences between Groups at T2, T3 and T4 (intention-to-treat, N = 92).*

| Outcome | Between-groups effect T2 [a] | | | | | Between-groups effect T3 [a] | | | | | Between-groups effect T4 [a] | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | ANCOVA [b] | | | | | ANCOVA [b] | | | | | ANCOVA [b] | |
| | Partial $\eta^2$ | Cohen's *d* | 95% CI | $F$ [c] | *P*-value | Partial $\eta^2$ | Cohen's *d* | 95% CI | $F$ [c] | *P*-value | Partial $\eta^2$ | Cohen's *d* | 95% CI | $F$ [c] | *P*-value |
| Panic and agoraphobia severity, self-rating (PAS) | 0.10 | 0.66 | 0.24 - 1.08 | 9.77 | <0.005 | 0.16 | 0.89 | 0.46 - 1.31 | 17.40 | <0.001 | 0.14 | 0.81 | 0.38 - 1.24 | 14.63 | <0.001 |
| Anxiety symptoms, observer-rating (HAM-A) | 0.03 | 0.42 | 0.01 - 0.84 | 3.97 | <0.05 | NA | NA | NA | NA | NA | 0.05 | 0.47 | 0.05 - 0.88 | 4.86 | <0.05 |
| Agoraphobic cognitions (ACQ) | 0.06 | 0.51 | 0.05 - 0.93 | 5.88 | <0.05 | 0.07 | 0.55 | 0.14 - 0.97 | 6.80 | <0.05 | 0.05 | 0.46 | 0.04 - 0.87 | 4.69 | <0.05 |
| Body sensations (BSQ) | 0.05 | 0.46 | 0.05 - 0.88 | 4.77 | <0.05 | 0.14 | 0.79 | 0.37 - 1.22 | 13.96 | <0.001 | 0.09 | 0.66 | 0.22 - 1.06 | 9.01 | <0.005 |
| Agoraphobic avoidance (MI), accompanied | 0.00 | 0.06 | -0.35 - 0.47 | 0.12 | 0.734 | 0.01 | 0.24 | -0.17 - 0.65 | 1.23 | 0.271 | 0.03 | 0.32 | -0.09 - 0.73 | 2.31 | 0.132 |
| Agoraphobic avoidance (MI), alone | 0.05 | 0.45 | 0.04 - 0.86 | 4.49 | <0.05 | 0.03 | 0.36 | -0.05 - 0.78 | 2.90 | 0.092 | 0.11 | 0.70 | 0.27 - 1.12 | 10.72 | <0.005 |
| Depressive symptoms (CES-D) | 0.01 | 0.18 | -0.23 - 0.59 | 0.75 | 0.389 | 0.00 | 0.11 | -0.30 - 0.52 | 0.24 | 0.624 | 0.06 | 0.49 | 0.07 - 0.90 | 5.37 | <0.05 |
| Quality of life (SF-12), physical health | 0.00 | 0.0 | -0.41 - 0.41 | 0.01 | 0.910 | 0.02 | 0.28 | -0.13 - 0.69 | 1.72 | 0.193 | 0.00 | 0.13 | -0.28 - 0.54 | 0.33 | 0.567 |
| Quality of life (SF-12), mental health | 0.02 | 0.25 | -0.16 - 0.66 | 1.39 | 0.242 | 0.02 | 0.31 | -0.10 - 0.66 | 2.23 | 0.139 | 0.11 | 0.70 | 0.28 - 1.12 | 10.98 | <0.005 |

*Note.* CI = confidence interval; ANCOVA = analysis of covariance; NA = not available
[a] Missing data imputed by multiple imputation.
[b] Controlling for pre-treatment scores (T1).
[c] Degrees of freedom not provided due to multiple imputation.

With regard to response, the reliable clinical change was not significant at post-measurement ($\chi^2$ [2, n = 92] = 2.52, $p$ > 0.05) (improvement: GET.ON Panic: n = 12 [26.67%] and WLC: n = 7 [14.89%]; deterioration: GET.ON Panic: n = 2 [4.44%] and WLC: n = 1 [2.13%]) nor at 3-month follow-up ($\chi^2$ [2, n = 92] = 5.30, $p$ > 0.05) (improvement: GET.ON Panic: n = 14 [31.11%] and WLC: n = 6 [12.77%]; deterioration: GET.ON Panic: n = 0 [0%] and WLC: n = 1 [2.13%]). However, the GET.ON Panic group was superior to the WLC regarding the percentage of participants attaining reliable clinical change (RCI = +/-10.68) in panic symptom severity at 6-month follow-up *($\chi^2$ [2, n = 92] = 7.11, $p$ < 0.05)* (improvement: GET.ON Panic: n = 22 [48.89%] and WLC: n = 12 [25.53%]; deterioration: (GET.ON Panic: n = 0 [0%] and WLC: n = 1 [2.13%]). These reliable clinical changes correspond to a *NNT* from baseline to post-treatment of *NNT* = 8.49 (95% CI 3.54 – >106), at 3-month follow-up of *NNT* = 5.45 (95% CI 2.87 – 55.78) and at 6-month follow-up of *NNT* = 4.28 (95% CI 2.35 – 24.07) respectively. Regarding the long term effect, these results indicate that four individuals had to participate in the GET.ON Panic training to result in one additional individual having reliable clinical improvement in panic symptom severity.

With regard to remission rates, at baseline nearly all participants (n = 90 [97.83%]) fulfilled the diagnostic criteria of PD. At 6-month follow-up, 70 participants (76.09%; GET.ON Panic group: n = 33 [47.14%], WLC: n = 37 [52.86%]) agreed to the telephone-administered diagnostic interview. In total, 15 participants (21.43%) were free of a diagnosis. There was a greater reduction in diagnoses in the GET.ON Panic group (n = 11 [33.33%]) compared to the WLC (n = 4 [10.81%]) *($\chi^2$ [1, n = 70] = 5.26, $p$ < 0.05)*.

**Additional Anxiety Measures**

Tables 3 and 4 display the means and the between group effects for all outcomes on all assessment points. Comparing the GET.ON Panic with the WLC group on further self-rated anxiety measurements, we found stronger between group effect sizes for agoraphobic cognitions (partial $\eta^2$ = 0.06, $d$ = 0.51, 95% CI 0.05 – 0.93) and bodily sensations (partial $\eta^2$ = 0.05, $d$ = 0.46, 95% CI 0.05 – 0.88) in the GET.ON Panic group compared with the WLC group at post-treatment. A difference on agoraphobic avoidance between the groups could only be found when participants had to manage difficult situations when they were alone with small effect sizes (partial $\eta^2$ = 0.05, $d$ = 0.45, 95% CI 0.04 – 0.86) at post-treatment as well as (partial $\eta^2$ = 0.03, $d$ = 0.36, 95% CI -0.05 – 0.78) at 3-month follow-up and a medium effect size (partial $\eta^2$ = 0.11, $d$ = 0.70, 95% CI 0.27 – 1.12) at 6-month follow-up. ANCOVA

did not reveal significance difference between the groups regarding agoraphobic avoidance when participants had to manage difficult situations when they were in companionship of other people.

**Additional Measures**

As shown in Tables 3 and 4, at post measurement as well as 3-month follow-up the GET.ON Panic group showed no significant reduction of depressive symptoms compared with the wait-list control group. However, at 6-month follow-up the depressive symptoms of the GET.ON Panic group decreased significantly with a small effect size compared with the WLC (partial $\eta^2 = 0.06$, $d = 0.49$ [95% CI 0.07 – 0.90]). Results on the quality of life scales with regard to mental health showed no reduction at post measurement as well as 3-month follow-up, but a medium reduction after 6 months (partial $\eta^2 = 0.11$, $d = 0.70$ [95% CI 0.28 – 1.12]). Further, no difference on symptoms regarding physical aspects of quality of life were found.

**App Usage and User Satisfaction**

The participants of the training group (n = 45) used the mobile diary 25.02 times during the 8 week training period on average (0.45 diary entries per day per participant). Repeated measure ANOVA did not reveal any changes in the diary scores over a period of 8 weeks. Furthermore, they were unrelated to the primary outcome. The participants performed an average of 148.80 ($SD = 279.34$, range 0 – 1702) interoceptive exposure exercises and 6.63 in-vivo exercises ($SD = 17.74$, range 0 – 113). A SUS score of M = 71.16 ($SD = 18.97$) as measured at post-treatment indicated good usability of the GET.ON Panic app. Overall, user satisfaction with the hybrid training was high (M = 28.10 [$SD = 5.09$]. For example, 91% of participants indicated that they would recommend the training to a friend in need.

## Discussion

The aim of the present study was to evaluate the efficacy of GET.ON Panic, a guided, mobile- and web-based CBT online training for adults suffering from significant PD symptoms. Results showed that individuals treated with GET.ON Panic experienced a significantly greater reduction of PD symptom severity than did participants of a wait-list control condition with between-group effect sizes of Cohen's. The findings also show that the effects were not only stable over time but even increased after the treatment was completed ($d/NNT = 0.66/8.49$ at post vs. $d/NNT = 0.89/5.45$ after 3 months and $d/NNT$

= 0.81/4.28 after six months). As such they fall well into the range of reported effect sizes in meta-analyses for internet-based interventions for PD (e.g., Andrews et al., 2010: $g = 0.83$; Andrews et al., 2018: $g = 1.31$; Haug et al., 2012: $g = 0.83$; Spek et al., 2007: $d = 0.96$). The findings also show that one out of three participants in the intervention group had attained complete remission of PD at the last assessment point whereas this was only the case in one out of ten participants in the control group. With regard to secondary outcomes, it is of note that the 6-month follow-up effects on depressive symptoms are larger than the average of effects reported for psychological treatment for depression (Cohen's $d = 0.49$ vs. Hedge's $g = 0.35$; Cuijpers et al., 2014). Finally, in the present study adherence rates and user satisfaction appear slightly higher than what has been reported in previous studies (adherence: 73 % vs. 66 %, satisfaction: 91 % vs. 86%; Andrews et al., 2018).

**Clinical Implications**

The results of this study suggest that a significant number of individuals suffering from symptoms of PD can be helped with an intervention that is comparatively easy to disseminate, that can be offered at comparatively low costs and that can be used anonymously which arguable lowers an important barrier to service utilization (Ebert et al., 2018). However, the results also show that about two thirds of participants were not completely recovered after the intervention. Thus, interventions such as GET.ON Panic might best be utilized in a stepped care framework in which patients failing to attain recovery through an internet-based intervention subsequently receive more intense (and costly) interventions (Bower & Gilbody, 2005).

A potential step-up could be the use of intervention that integrate hybrid online training into f2f CBT (Marks, Kenwright, McDonough, Whittaker, & Mataix-Cols, 2004). In such blended interventions, therapists might fully exploit the potential of utilizing the EMA data provided by the smartphone as well as the potential of EMIs that are derived from individual case formulations and carried into the patient's life with the help of their mobile devices (Bruinsma, Kampman, Exterkate, & Hendriks, 2016). The finding that adherence and utilization rates found the present study appear superior to what it currently reported for desktop-based iCBT interventions is consistent with the rapidly shifting use of the internet away from desktop-based towards mobile devices (ITU, 2017, World Health Organization [WHO], 2011) and suggests that the future iCBT interventions should at least include a mobile component.

The findings that depressive symptom severity was significantly reduced in the intervention group is important as many individuals suffering from PD also suffer from other mental health problems such as depression (Kessler, Chiu, Demler, Merikangas, & Walters, 2005). As co-occurring disorders may mutually help maintain each other (Kessler et al., 1998; Kinley et al., 2011), it is important that co-morbid conditions are treated along with the primary disorder. The positive effects of the hybrid intervention evaluated in the present study on depression are consisted with findings from CBT that successfully treating PD also results in a reduction of depressive symptoms (Walderhaug, Gjestad, Egeland, Havik, & Nordgreen, 2019, Allen, et al., 2010).

**Strengths and Limitations**

To our knowledge, this is the first study examining the efficacy of an iCBT training making use of mobile components in a target group of people with mild to moderate panic and agoraphobia symptoms. One of the main strengths of this study is its solid study design testing a newly developed training within an RCT against a WLC. In addition to self-rating outcomes, we conducted clinical interviews with regard to symptom severity and change of diagnostic status over a period of six months and an observer-rated anxiety outcome to validate the outcomes based on self-ratings. Further, this study has a high ecological validity as participants used their own smartphones. They were supposed to interact with their smartphone as they would normally do. This may lead to a higher acceptance of and satisfaction with the GET.ON Panic training and foster the integration of psychological interventions into the daily life of individuals. The overall low drop-out rates in this study support this assumption.

This study has several limitations that need to be considered. First, the study results cannot be generalized to all individuals suffering from PD symptoms. Participants partaking in this trial actively subscribed for participation and underwent an extended eligibility procedure prior to the study. Many interested individuals were excluded according to the criteria defined in the study protocol. Thus, we assume that the current participants represent a more intrinsically motivated study sample and, in addition, have a higher affinity for the internet than the average individuals suffering from PD. The external validity of the present study might therefore be limited. Secondly, for future treatment development it would have been of interest to compare the hybrid intervention with both an exclusively desktop-based and an exclusively mobile-based intervention for PD. As such a design, however, was beyond

what we could realize in this study, it would need to be used in subsequent studies. Such studies should also compare the efficacy (and cost-effectiveness) of desktop/mobile-based, hybrid and blended interventions with f2f therapy for PD. Thirdly, we cannot draw any conclusions on the efficacy beyond the 6-month follow-up assessment. Thus, futures studies should evaluate long-term effects of hybrid iCBT interventions for PD.

# References

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# Kapitel 5: Allgemeine Diskussion

Symptome einer Panikstörung bringen eine hohe individuelle Belastung sowie große gesellschaftliche Herausforderungen mit sich. Internetbasierte Interventionen stellen eine innovative Maßnahme dar, um von Panikstörungen betroffenen Personen niedrigschwellig und wirksam zu helfen. So konnte die Evidenz von internetbasierten Intervention für Panikstörung und Agoraphobie in zahlreichen Studien bestätigt werden.

Smartphonebasierte Technologien bergen ein erhebliches Potenzial, um die Zugänglichkeit und Wirksamkeit internetbasierter Interventionen weiter zu verbessern. Die Ziele dieser Dissertation waren vor diesem Hintergrund (I) die Entwicklung eines hybriden Online-Trainings für Personen, die unter Panik- und Agoraphobiesymptomen leiden, (II) die Entwicklung und Überprüfung der Machbarkeit einer mobilen Smartphone-App bei Panikstörung und Agoraphobie, sowie (III) die Überprüfung der Wirksamkeit des hybriden Online-Trainings bei Panikstörung und Agoraphobie.

In diesem abschließenden Kapitel werden die wichtigsten Ergebnisse der im Rahmen dieser Arbeit durchgeführten Studien zusammengefasst und mit vorherigen Forschungsergebnissen verglichen. Des Weiteren werden die Limitationen der durchgeführten Studien sowie die Implikationen für die Implementierung in die klinische Praxis und für zukünftige Forschung diskutiert.

## Zusammenfassung der Ergebnisse der Machbarkeitsstudie (Kapitel 2)

Die GET.ON Panik App wurde in einem interdisziplinären Team aus PsychologInnen, Informatikern und Designern in einem iterativen Prozess entwickelt (Kleine Stegemann, Ebenfeld, Lehr, Berking, & Funk, 2013) und in einer anschließenden explorativen Machbarkeitsstudie mit 10 Teilnehmenden initial untersucht (Ebenfeld et al., 2020). Die Kombination von quantitativen und qualitativen Daten führte zu Erkenntnissen darüber, wie die Teilnehmenden eine Gesundheits-App nutzen.

### Entwicklung der GET.ON Panik App

Wie in Kapitel 1 beschrieben, weisen rein browserbasierte Online-Trainings Grenzen in Bezug auf die Unterstützung der Betroffenen in ihrem täglichen Leben auf. Für Panikstörung und Agoraphobie konnten wir insbesondere zwei Problembereiche identifizieren, für die die Integration mobiler Komponenten in das Training eine sinnvolle Erweiterung verspricht. Zum einen fehlt es in den meisten bekannten Online-Trainings an einem Echtzeit-Monitoring von Panikattacken. Zum anderen bieten die meisten Online-Trainings keine

Vor-Ort-Unterstützung während Selbstexpositionsübungen. Die GET.ON Panik App besteht darum aus einem mobilen Tagebuch und einem mobilen Expositionsbegleiter.

Mit Hilfe des mobilen Tagebuchs können Teilnehmende akute Panikattacken dokumentieren sowie Zusammenfassungen ihres Tages hinsichtlich Angsterleben und Stimmung festhalten. Bei der Dokumentation von Panikattacken werden Teilnehmende mit verschiedenen Fragen zu der Attacke durch den Eintrag geleitet. Zusätzlich haben sie die Möglichkeit, ein Foto von der angstauslösenden Situation zu machen oder eine schriftliche Notiz zu ergänzen, um sich an bestimmte Aspekte der Situation rückwirkend besser zu erinnern. Für die täglichen Zusammenfassungen wurde ein Terminkalender mit festen Terminen implementiert. Die Teilnehmenden wurden gebeten, jeden Tag, vorzugsweise abends, eine feste Uhrzeit zu wählen, an der sie über den vergangenen Tag nachdenken und eine tägliche Zusammenfassung ausfüllen. Um die Entwicklung und den Fortschritt des Teilnehmenden zu visualisieren, zeichnet die App die täglichen Zusammenfassungen auf und stellt diese in Verlaufsgrafiken dar.

Der Expositionsbegleiter bietet Unterstützung für interozeptive und in-vivo Expositionen. Er führt die NutzerIn durch eine Abfolge von Schritten und bietet gleichzeitig Anweisungen und Orientierung für die Durchführung. Darüber hinaus wird der Teilnehmende an bestimmten Stellen gebeten, Fragen zu beantworten, um zu messen, ob die Exposition korrekt durchgeführt wurde (z. B. Angstzustand, Vermeidungsgrad und Schwere der Körpersymptome). Nach einer in-vivo Exposition erhalten die Teilnehmenden ein Feedback, um zu sehen, ob die Übung funktioniert hat, und um die Situation zu reflektieren. Außerdem haben sie die Möglichkeit, ein Foto von der geschafften Situation zu machen. Teilnehmende können sich diese Fotos zusammen mit dem Feedback und einer Beschreibung der Situation in einer Fotogalerie anzeigen lassen. Zudem wird die Anzahl der Expositionsübungen in den Plot zur Verlaufsdiagnostik integriert, um mögliche Zusammenhänge zwischen Übungsanzahl und Verlauf der Angstsymptomatik sehen und verstehen zu können.

**Machbarkeit und Nutzen der GET.ON Panik App**

Die meisten Teilnehmenden betrachteten die GET.ON Panik App insgesamt als praktikables Trainingsmittel. Die täglichen Zusammenfassungen sowie die interozeptiven Expositionsübungen waren sowohl die am meisten genutzten als auch am besten bewerteten Komponenten der App. Alle Teilnehmenden gaben an, dass sie diese Übungen nicht so oft

ohne die App gemacht hätten. Die App scheint somit die Trainingsadhärenz zu verbessern sowie eine motivierende Funktion zu erfüllen. Hohe bis sehr hohe Bewertungen in Bezug auf Trainingszufriedenheit (CSQ-I=30,13, SD=1,64), Benutzerfreundlichkeit (SUS=84,06, SD=13,36) und Technologieakzeptanz (wahrgenommener Nutzen: M=6,13, SD=0,75; wahrgenommene Bedienbarkeit: M=6,09, SD=1,24; wahrgenommener Spaß M=5,89, SD=0,91) unterstützen diese Ergebnisse.

Jedoch wurden andere Komponenten der App als weniger hilfreich empfunden. Die Teilnehmenden hatten beispielsweise Probleme bei der Echtzeit-Registrierung von Panikattacken. Als einer der wichtigsten Gründe wurde hierfür angeführt, dass die betroffenen Personen derzeit überhaupt nicht unter Panikattacken litten und in diesem Falle keine Einträge machen konnten. Als weitere Begründung wurde die Schwierigkeit berichtet, dass die App während bzw. unmittelbar nach einer Panikattacke aufgrund von akuten Erregungszuständen schwierig zu bedienen sei.

Auch bei der Durchführung von in-vivo Expositionen gibt es Verbesserungspotenzial. Die wohl wichtigste Erkenntnis ist, dass eine Synchronisierung der Daten zwischen App und Training gefehlt hat, um die Benutzerfreundlichkeit zu verbessern. Der Nutzen der Fotofunktion als Teil der Dokumentation der Angstzustände oder während der in-vivo Exposition wurde von den Teilnehmenden als unwichtig bewertet. Die meisten von ihnen nutzten es nicht oder betrachteten es als „lustiges Gadget". Im Gegensatz zu unseren ursprünglichen Annahmen scheint eine Fotofunktion kein wirksames Mittel zu sein, um die Übertragung des Trainings in den Alltag der Teilnehmenden zu verbessern.

Im Großen und Ganzen empfanden alle befragten Teilnehmenden die Kombination aus mobilem Tool und browserbasiertem Training als kohärent und sehr motivierend. Insbesondere Expositionsübungen und das Erhalten des grafischen Verlaufsfeedbacks, nachdem sie diese Aufgabe ausgeführt hatten, halfen ihnen, die körperlichen Symptome während einer Panik- oder Angstattacke zu verstehen und dies in ihren Alltag zu transportieren.

Einige der genannten Schwierigkeiten konnten wir unmittelbar nach der Machbarkeitsstudie beheben, so dass wir in der folgenden randomisierten kontrollierten Studie bereits eine überarbeitete Version der App einsetzen konnten. Als größte Änderung kann die Integration einer mobilen Atem- und Muskelentspannung angeführt werden, die den Teilnehmenden die Möglichkeit geboten hat, barrierefrei zu jeder Zeit an jedem Ort auf Entspannungsübungen

zuzugreifen. Des Weiteren wurde ein *Reminder* für die täglichen Zusammenfassungen integriert. Die Teilnehmenden konnten von nun an, zu einer von ihnen definierten Zeit sich per Audiosignal an die täglichen Eintragungen erinnern.

## Zusammenfassung der Ergebnisse der Wirksamkeitsstudie (Kapitel 4)

Zur Überprüfung der Wirksamkeit des hybriden Online-Trainings GET.ON Panik wurde eine randomisierte kontrollierte Studie durchgeführt. Das dazugehörige Studienprotokoll (Ebenfeld et al., 2014) ist in Kapitel 3 zu finden. Insgesamt wurden 92 Personen mit mild bis moderat ausgeprägten Paniksymptomen (PAS score: 9-28) in die Studie aufgenommen und in einen der beiden Studienarme unterteilt: die Interventionsgruppe, die das hybride Online-Training als begleitete Selbsthilfe erhielt und die Kontrollgruppe, die nach einer 6-monatigen Wartezeit Zugang zu dem Training bekam. Das Durchschnittsalter der Studienteilnehmenden betrug 38 Jahre (SD=10,42), knapp mehr als die Hälfte waren Frauen (n=51, 55%). Bei 83% der Teilnehmenden lag laut SKID-Interview eine Panikstörung mit Agoraphobie, bei 13% eine Panikstörung ohne Agoraphobie und bei 2% lagen lediglich subklinische Symptome, jedoch keine voll diagnostizierbare Panikstörung vor. Deutlich über die Hälfte aller Teilnehmenden (n=58, 63%) hat zuvor schon einmal psychotherapeutische Hilfe in Anspruch genommen.

In beiden Studiengruppen zeigte sich eine Reduktion der Paniksymptome acht Wochen nach der Randomisierung; für die Kontrollgruppe um 2,23 Punkte und für die Interventionsgruppe um 6,21 Punkte auf der Panik- und Agoraphobie-Skala. Dabei verbesserte sich die Schwere der Paniksymptome für Teilnehmende aus der Interventionsgruppe deutlich stärker als bei Teilnehmenden der Kontrollgruppe (F=9,77, p<0,01; d=0,66, 95% KI 0,24-1,08). Dieser Effekt wurde zum 3-Monats-Messzeitpunkt noch stärker (F=17,40, p<0,001; d=0,89, 95% KI 0,46-1,31) und hielt sich bis zum 6-Monats-Messzeitpunkt (F=14,63, p<0,001; d=0.81, 95% KI 0,38-1,24) relativ konstant. Diese Effektstärke ist statistisch als groß einzuordnen. Zudem waren signifikant mehr Personen der Interventionsgruppe (33,33%) symptomfrei zum 6-Monats-Messzeitpunkt im Vergleich zur Kontrollgruppe (10,81%) ($x^2$[1,n=70]=4.00, p< 0,05). Darüber hinaus wiesen Personen in den Trainingsgruppen im Vergleich zu denen der Kontrollgruppe eine signifikante Reduktion der Angst gemessen durch Fremdbeurteilung (d=0,47, 95% KI 0,05-0,88), agoraphobische Kognitionen (d=0,46, 95% KI 0,04-0,87) körperbezogene Ängste (d=0,66, 95% KI 0,22-1,06), agoraphobische Vermeidung (unbegleitet) (d=0,70, 95% KI

0,27-1,12), depressiver Symptomatik (d=0,49, 95% KI 0,07-0,90) und Verbesserung der Lebensqualität (d=0,70, 95% KI 0,14-0,55) zum 6-Monats-Messzeitpunkt auf.

Die Trainingsadhärenz war allgemein hoch. Teilnehmende absolvierten durchschnittlich 5,11 der insgesamt 6 Trainingslektionen, von ihnen durchliefen 33 Personen (73,33%) das komplette Training. Auch die Teilnehmerzufriedenheit war hoch (CSQ-I Summenwert=28,10, SD=5,09). Von den Teilnehmenden würden 91% das Training einem Freund oder einer Freundin weiterempfehlen. Ein Durchschnittswert von 71.16 (SD=18,97) auf der System Usability Scale deutet zudem auf eine gute Nutzbarkeit der mobilen Komponente hin. *Trackings* zur App-Nutzung währen der 8-wöchigen Trainingsdauer zeigten, dass jeder Teilnehmende durchschnittlich 148,80 (SD=279,34, Range 0-1702) interozeptive Expositionsübungen und 6,63 in-vivo Expositionsübungen (SD = 17,74, Range 0-113) durchgeführt hatte. Das mobile Tagebuch wurde im Durchschnitt 0,45 Mal pro Tag und pro Teilnehmenden genutzt. Jedoch wurden keine Veränderungen der Tagebuchwerte im Laufe der Zeit festgestellt. Darüber hinaus hatten die Tagebuchratings keinen Zusammenhang zu primären und sekundären Endpunkten.

## Bedeutung der Ergebnisse und Einordnung in die bisherige Forschung

### Demografie

Die Verteilung von Männer und Frauen war über beide Studien hinweg nahezu ausgewogen. In der Machbarkeitsstudie (Kapitel 2) lag der Frauenanteil bei exakt 50%, in der Wirksamkeitsstudie (Kapitel 4) bei 55,4%. Dieser Befund ist in zwei Hinsichten auffällig: Erstens, Frauen sind in der Allgemeinbevölkerung ungefähr doppelt so häufig von Panikstörung betroffen als Männer (Wittchen et al., 2011). Demnach wäre davon auszugehen, dass sich bei GET.ON Panik ebenfalls ein doppelt so hoher, oder zumindest wesentlich höherer, Frauenanteil vorfinden lässt. Zweitens, geht aus der bestehenden Literatur hervor, dass bei der Inanspruchnahme von Hilfsangeboten, wie internetbasierte Selbsthilfetrainings, der Frauenanteil im Allgemeinen bei um die 70% liegt (u. a. Haug, Nordgreen, Öst, & Havik, 2012). Mit Blick auf vergleichbare hybride Behandlungsangebote aus anderen Ländern, finden sich Frauenanteile von 64,5% (Ivanova et al., 2016), 70% (Proudfoot et al., 2013) und 84% (Christoforou, Sáez Fonseca, & Tsakanikos, 2017). Über die Gründe, wieso vergleichsweise viele Männer bzw. wenig Frauen GET.ON Panik nutzten, können lediglich Mutmaßungen angestellt werden. Ob die auf Stereotypen beruhende

Annahme einer hohen Technikaffinität von Männern, reiner Zufall oder ganz andere Ursachen das Geschlechterverhältnis erklären, bleibt offen und sollte mit späteren Studien verglichen werden.

Weiterhin war auffällig, dass 63% der Teilnehmenden bereits Erfahrungen mit Psychotherapie hatten. Zudem lag bei 98% aller Teilnehmenden eine voll diagnostizierbare Panikstörung (davon 85% ebenfalls mit Agoraphobie) vor. Dies deutet darauf hin, dass die Stichprobe wesentlich therapieerfahrener und klinisch erkrankter waren als ursprünglich bei Personen mit mild bis moderat ausgeprägtem Beschwerdeniveau gemessen zum Baseline-Zeitpunkt angenommen. Dies zeigt, dass internetbasierte Interventionen nicht nur Personen außerhalb psychosozialer Versorgungsstrukturen ansprechen (McKellar, Austin, & Moos, 2012), sondern auch ein attraktives Angebot für Menschen, die bereits Therapieerfahrung haben, sein kann.

Das Durchschnittsalter der Studienteilnehmenden (Kapitel 4) von 38 Jahren sowie der hohe Bildungsgrad (65% mit Allgemeiner Hochschulreife) ist konsistent mit vorhandenen Metaanalysen (Haug et al., 2012) und vergleichbaren Studien (Christoforou et al., 2017; Ivanova et al., 2016; Proudfoot et al., 2013).

Insgesamt lässt sich festhalten, dass das Trainingsangebot gebildete, therapieerfahrene Männer Ende 30, bei denen eine diagnostizierbare Panikstörung mit Agoraphobie vorlag, besonders angesprochen hat.

### Adhärenz[4], Drop-out und Zufriedenheit

Hoher Trainings- sowie Studienabbruch wird häufig als Herausforderung bei internetbasierten Selbsthilfe-Trainings genannt (Melville, Casey, & Kavanagh, 2010). Aus diesem Grund sollten neben Maßen, wie Effektstärken, auch Adhärenz-, Abbruchraten und die Teilnahmezufriedenheit zur Bewertung der Effektivität und Akzeptanz eines Online-Trainings herangezogen werden (Hilvert-Bruce, Rossouw, Wong, Sunderland, & Andrews, 2012). Die kürzlich erschienene Metaanalyse von Apolinário-Hagen (2019) legt ein besonderes Augenmerk auf Adhärenz von internetbasierten Paniktrainings und zeigt, dass

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[4] Adhärenz wird in der Literatur häufig nicht einheitlich definiert. In diese Arbeit wurde sich dazu entschieden, Adhärenz mit Trainingsadhärenz gleichzusetzen und steht als Maß für das Einhalten des Trainings. Die Trainingsadhärenz wird als Anteil (in %) an Teilnehmenden angegeben, die das Training komplett absolviert haben. Drop-out hingegen bezieht sich auf die Studienadhärenz und misst den Studienabbruch im Sinne von unbeantworteten Befragungen zum entsprechenden Messzeitpunkt.

es eine große Varianz in Bezug auf die Trainingsadhärenz über verschiedene Studien hinweg gab (7,8% [Ivanova et al., 2016] - 75% [Berger, Boettcher, & Caspar, 2014]). In der vorliegenden Wirksamkeitsstudie absolvierten 73% der Teilnehmenden das Training GET.ON Panik vollständig (6 Lektionen). Im Durchschnitt betrug die Anzahl abgeschlossener Lektionen 5,11. Die Adhärenz war also durchaus zufriedenstellend und befand sich im oberen Bereich von denen anderer internetbasierter Paniktrainings. Auch bei den Drop-out Raten konnte Apolinário-Hagen (2019) eine hohe Varianz feststellen, sie reichten von 9,8% (Berger et al., 2014) bis 42,1% (van Ballegooijen et al., 2013). Abbruchraten in Bezug auf die Studienadhärenz waren bei GET.ON Panik ebenfalls eher gering. Der Drop-out lag bei 8,7% zur Postbefragung, 18,5% zur 3-Monats- und 21,7% aller Teilnehmenden zur 6-Monats-Katamnese vor. Die Zufriedenheit der Teilnehmenden mit dem Online-Training war in dieser Studie hoch, was sich insgesamt auch in anderen Studien bestätigen ließ (Andrews et al., 2018; Apolinário-Hagen, 2019).

**Machbarkeit und Nutzung der App**

Die Ergebnisse der Machbarkeitsstudie aus Kapitel 2 legen nahe, dass der Nutzen der in das hybride Online-Training integrierten GET.ON Panik App die täglichen Routineaufgaben während des Trainings erleichtern kann. So konnte die App beispielsweise kontinuierlich bei interozeptiven Expositionsübungen oder beim abendlichen Erfassen der allgemeinen Angst und Stimmung eingesetzt werden. Im Gegensatz dazu wurde die Eingabe von Daten, die weniger vorhersehbar und ereignisbezogener waren, wie in der in-vivo Exposition oder beim Symptommonitoring unmittelbar nach Panikattacken, als schwieriger empfunden. Diese Ergebnisse stimmte mit denen von Morrison et al. (2014) überein. Sie gaben an, dass ihre POWeR-Tracker-App für bestimmte, sich wiederholende Verhaltensweisen ebenfalls stärker genutzt wurde. In der Wirksamkeitsstudie ließen sich ähnliche Ergebnisse finden. Auch in dieser Studie beurteilten die Teilnehmenden die App als sehr nützlich. Interessanterweise nutzten sie die App insgesamt etwa 25 Wochen, was weit über den Trainingszeitraum hinausgeht.

Die ursprüngliche Annahme war, dass die GET.ON Panik App als Instrument für ambulante Assessments (EMA) eingesetzt werden kann. Diese Annahme konnte jedoch so nicht bestätigt werden. Teilnehmende hatten während der Trainingsdauer entweder nur wenig akute Panikattacken oder berichteten von Schwierigkeiten mit der Handhabung der App bei gleichzeitig hohen Erregungszuständen. Folglich war ein ambulantes Assessment der akuten

Paniksymptome mit Hilfe der App nicht möglich. Ergänzend zur Messung von akuten Paniksymptomen, verfügte die App über die Möglichkeit eine Tagesbilanz zu erfassen, welche ursprünglich dafür konzipiert wurde, um den Symptomverlauf von Angst, Vermeidung und Stimmung in Form von täglichen Zusammenfassungen zu monitorieren. Diese Funktion wurde zwar – wenn auch nicht täglich – genutzt, konnte jedoch nicht zu einer validen Messung der Symptome und deren Verlauf beitragen. Die gemessenen Baseline-Werte[5] waren mit 8 von 10 möglichen Punkten unerwartet hoch für Personen, die sich für eine Paniktraining anmeldeten. Zudem zeigte sich im weiteren Laufe der Trainings keine Veränderung der Tagebuchwerte. Der Angstfrei-Wert lag durchgängig konstant bei 8 Punkten. Die Belastung, wie sie zu den verschiedene Messzeitpunkten durch validierte Fragebögen und Interviews gemessen wurde, konnte durch die Tagebuch-Einträge nicht widergespiegelt werden. Die Tagebuch-Werte korrelierten zu keinem Zeitpunkt mit den Werten der Fragebögen-Erhebungen.

Daher ist davon auszugehen, dass die App zwar als überzeugende Technologie (Fogg, 2003; Fogg & Eckles, 2007; Kelders, Kok, Ossebaard, & Van Gemert-Pijnen, 2012) die Teilnehmenden in das Online-Training eingebunden hat und indirekt zum Trainingserfolg in Bezug auf die Wirksamkeit sowie Adhärenz beigetragen hat, jedoch kein Instrument darstellt, das den Symptomverlauf im Sinne von EMA-Messungen valide abbilden konnte.

**Wirksamkeit**

Personen, die an dem Online-Training GET.ON Panik teilgenommen haben, wiesen mit einer Effektstärke von Cohen's d=0,66 signifikant weniger Panikbeschwerden als Teilnehmende aus der Kontrollgruppe auf. Dieser Effekt verstärkt sich zur 3-Monats-Katamnese auf eine Effektstärke von Cohen's d=0,89. Nach 6 Monaten findet sich immer noch ein Effekt von Cohen's d=0,81. Verglichen mit der jüngsten Metaanalyse von Andrews et al. (2018) war die Verbesserung der Paniksymptome in der GET.ON Panik Studie weniger ausgeprägt als bei anderen internetbasierten (browserbasierten) Paniktrainings. Die in diese Metaanalyse einbezogenen Studien zeigten jedoch eine hohe Heterogenität hinsichtlich des Schweregrades der Paniksymptome bei Studienbeginn. Viele dieser Studien wiesen zu Beginn einen höheren Schweregrad der Panik auf (z. B. Carlbring, Westling, Ljungstrand, Ekselius,

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[5] Mit Baseline-Werten werden Werte aller Messungen zu Angst und Vermeidung aus Woche 1 gemeint, welche zu einem Angstfrei-Wert aggregiert wurden. Je höher der Wert auf der 10-Punkte Likert Skala desto weniger Angstsymptomatik.

& Andersson, 2001; Klein, Richards, & Austin, 2006), wodurch mehr Raum für Verbesserungen gelassen wurde. Dadurch ist die Vergleichbarkeit eingeschränkt. Die bei GET.ON Panik gefundenen 3- und 6-Monats-Effekte sind jedoch mit den Ergebnissen älteren Metaanalysen durchaus konsistent (Andrews, Cuijpers, Craske, McEvoy, & Titov, 2010; Haug et al., 2012; Spek et al., 2007). Dies deutet darauf hin, dass das hybride Training GET.ON Panik in Bezug auf die Reduktion von Paniksymptomen ähnlich wirksam ist wie andere, bekannte internetbasierte Trainings bei Panikstörung.

Wenngleich es aufgrund unterschiedlicher Studiendesigns und theoretischer Therapierationalen schwierig ist, die in dieser Arbeit gefundenen Effektstärken mit denen der wenigen vorhandenen Studien zu hybriden Online-Trainings zu vergleichen, wurde bei GET.ON Panik eine größere Reduktion der Panikbeschwerden gefunden im Vergleich zu den Studien von Proudfoot et al. (2013) (d=0,29-0,47) und Ivanova et al. (2016) (d = 0,05); und eine vergleichbare Reduktion der Beschwerden wie bei Christoforou et al. (2017) (10 Punkte Rückgang auf PAS in der Agoraphobie-Gruppe). In einer Metaanalyse zu smartphonebasierten Interventionen wurde eine deutlich geringere Reduktion von Angstsymptomen (g=0,45, Firth et al., 2017) nachgewiesen als es GET.ON Panik zeigte.

In Bezug auf weitere sekundäre Endpunkte gelang es dem hybriden Online-Training GET.ON Panik depressive Beschwerden und die Lebensqualität (hinsichtlich der psychischen Gesundheit) langfristig im Verlauf von 6 Monaten zu verbessern. Diese Effekte waren zu früheren Messzeitpunkten, nach 2 und 3 Monaten, noch nicht sichtbar. Vergleicht man dieses Ergebnis mit der Psychotherapie für subklinische Depression im Allgemeinen (Hedge's g=0,35, Cuijpers et al., 2014), haben wir eine etwas höhere Verbesserung festgestellt. In Bezug auf die Lebensqualität verbesserten sich die Teilnehmenden der GET.ON Panik-Gruppe ebenfalls nur am 6-Monats-Messzeitpunkt. Mit dem entsprechenden Cohen's d von 0,70 wurde eine etwas höhere Effektgröße als bei transdiagnostischen Ansätzen zur Behandlung von Angst und Depression angezeigt (Hedge's g=0,46, Newby, Mewton, Williams & Andrews, 2014).

Zusammengenommen deuten die Ergebnisse dieser Arbeit darauf hin, dass das hybride Online-Training GET.ON Panik dargereicht als Selbsthilfe-Training mit Coaching Unterstützung bei einer Zielgruppe mit mild bis moderat ausgeprägten Ausgangsbeschwerden wirksam zur Reduktion von Paniksymptomen im Vergleich zu einer Wartelisten-Kontrollgruppe mit uneingeschränktem Zugang zu Treatment-as-usual sein

kann. Diese Ergebnisse zeigen sich zur Katamnese nach 3 Monaten noch einmal verbessert und nach 6 Monaten insgesamt stabil. Teilnehmende, die das Training erhalten haben, sind zudem nach 6 Monaten weniger depressiv und haben eine deutlich höhere Lebensqualität gewonnen im Vergleich zu Personen, die das Training nicht bekommen haben. Die klinische Wirksamkeit ist vergleichbar mit der von bekannten interbasierten Interventionen und ist der von ersten anderen hybriden Trainings leicht überlegen – jedoch ist die Vergleichbarkeit aus methodologischen Gründen eingeschränkt.

Bisweilen ungewöhnlich ist das Phänomen der verzögerten Trainingswirksamkeit bei sowohl der Verbesserung der Panikbeschwerden als auch bei den Depressionswerten und der Lebensqualität in der hier vorliegenden Stichprobe. Dies könnte zum einen dadurch erklärt werden, dass einige Teilnehmende das Training zum Post-Messpunkt noch nicht vollständig durchlaufen hatten und sich der Trainingseffekt erst bei der nächsten Erhebung, welche bereits vier Wochen später stattfand, zeigen konnte. Zum anderen, ist es gut möglich, dass sich bestimmte Trainingseffekte erst verstetigen bzw. in den Alltag der Betroffenen transferiert werden mussten. So könnte es sein, dass Personen während der aktiven Trainingsperiode beispielsweise psychoedukative Inhalte über Panikstörung gelernt oder aufgefrischt und mit Hilfe der App erste Expositionsübungen ausgeführt haben. Jedoch erst außerhalb des geschützten Rahmen des Trainings, hatten Personen die Möglichkeit, das Gelernte unter ‚Realbedingungen' einzusetzen. So konnten sie in ihrem Alltag wiederholt die Erfahrung machen, dass die Angstsymptome unbedenklich sind und mit der Zeit weniger wurden oder vielleicht sogar gar nicht mehr auftraten. Auch die nachgelagerte Verbesserung der Werte von Lebensqualität und Depression sprechen dafür, dass Betroffene eine nachhaltige Verbesserung durch das Training erzielen konnten und es den Personen merklich besser geht. Aufgrund der sehr praktisch ausgelegten Funktionen der App sowie der hohen Nutzungsraten auch außerhalb der aktiven Trainingsperiode liegt es nahe, dass die mobile Technologie sowie die Kernfunktionen der App zum Trainingseffekt beigetragen haben und den Transfer in den Alltag der Betroffenen nachhaltig erleichterten.

## Limitationen

Bei der Interpretation der Ergebnisse dieser Arbeit müssen Limitationen berücksichtigt werden.

### *Eingeschränkte Generalisierbarkeit durch Selbstselektion und hohen Studienausschluss*

Alle Studienteilnehmenden haben sich selbst und aktiv für die Teilnahme angemeldet. Zudem wurden während des Rekrutierungsprozesses viele interessierte Personen gemäß des Studienprotokolls ausgeschlossen, da sie nicht die Studienvoraussetzungen erfüllten. So ist davon auszugehen, dass die Teilnehmenden in einigen Merkmalen anders sind als der Durchschnitt der betroffenen Personen aus der Allgemeinbevölkerung, die normalerweise an einer Teilnahme an einem Online-Paniktraining interessiert wären. Es ist daher möglich, dass die Studienpopulation zum einen eine intrinsisch motiviertere Stichprobe darstellt und zum anderen einen geringeren Schweregrad sowie weniger Komorbiditäten aufweist als die Normbevölkerung. Die externe Validität der Studienergebnisse kann daher eingeschränkt sein.

### *Keine Rückschlüsse über Wirksamkeit im direkten Vergleich möglich*

Zur Überprüfung der Wirksamkeit wurde eine randomisierte kontrollierte Studie mit Wartelisten-Kontrollbedingung durchgeführt. Da die Intervention neu und innovativ war, wurde diese ‚schwache' Vergleichsbedingung bewusst gewählt. Nichtsdestotrotz verbesserte sich die Kontrollbedingung im Laufe der Studie ebenfalls deutlich, was durch die erfahrene Aufmerksamkeit im Rahmen der Erhebungen (zu drei Messzeitpunkten wurden klinische Interviews à mindestens 30 Minuten durchgeführt) erklärt werden könnte. Schlussfolgerungen in Bezug auf den Nutzen des hybriden Trainingsformats gegenüber aktiven Kontrollgruppen, etwa einem browserbasierten Online-Training, Treatment-as-usual, Pharmakotherapie oder kognitiver Verhaltenstherapie im face-to-face Kontext können aus der Studie jedoch nicht gezogen werden.

### *Stichprobe zu klein für Subgruppenanalysen*

Die Stichprobengröße wurde mit Hilfe einer vorherigen Power-Analyse berechnet. Bei einer erwarteten Effektstärke von Cohen's d=0,6 (1-ß=80%) des primären Endpunktes, müssen 90 Personen in die Studie eingeschlossen werden. Diese Stichprobengröße lässt allerdings keine Subgruppenanalysen zu und war für Mediatoren- und Moderatoren-Analysen nicht ausreichend *gepowered*. Aus strukturellen und organisatorischen Gründen konnte die Stichprobengröße nicht beliebig erweitert werden, da sonst der antizipierte technische Support, der durch die App entstehen würde, nicht hätte bewerkstelligt werden können.

*Beobachtungszeitraum beschränkt sich auf 6 Monate*

In der vorliegenden Wirksamkeitsstudie wurde ein Erhebungszeitraum von maximal 6 Monaten durchgeführt, da die Kontrollgruppe aus ethischen Gründen nicht länger als diese Zeitspanne warten gelassen werden sollte, bis sie Zugang zur Intervention erhielt. Schlussfolgerungen hinsichtlich der Wirksamkeit des Trainings über diese Zeit hinaus sind nicht möglich.

## Von Innovation zur Implementation

Das hybride Online-Training GET.ON Panik hat sich in einer ersten randomisierten kontrollierten Studie als wirksam in der Reduktion von Paniksymptomen und weiteren sekundären Endpunkten, wie etwa Depression sowie in der Verbesserung der Lebensqualität herausgestellt. Die Effekte stiegen sogar über einen Zeitraum von 3 und 6 Monaten weiter an. Die Einbindung einer mobilen App in das Training erfuhr eine hohe Akzeptanz bei den Teilnehmenden und erwies sich als hilfreich, um Personen beim Selbstmonitoring sowie bei der Selbstexposition zu unterstützen. Die aktuellen Ergebnisse weisen darauf hin, dass GET.ON Panik zukünftig weiteren Betroffenen als wirksames Selbsthilfe-Tool zur Verfügung gestellt werden kann.

Nachfolgend werden Implikationen, die sich aus dieser Arbeit für die Praxis ableiten lassen, vorgestellt. Ebenfalls soll ein Ausblick auf neue Forschungsfragen sowie eine Weiterentwicklung der App geboten werden.

### Implikationen für die klinische Praxis

Die Ergebnisse dieser Arbeit legen nahe, dass das hybride Online-Training GET.ON Panik in den folgenden zwei klinischen Szenarien angewendet werden könnte.

*GET.ON Panik in der gestuften Versorgung*

GET.ON Panik kann ein Interventionsangebot darstellen, das sich an Betroffene im Rahmen einer gestuften Versorgung (*stepped-care*) (Haugh et al., 2019; Salomonsson et al., 2018) wendet. Im Sinne von stepped-care kann ein internetbasiertes Training vor ambulanter Psychotherapie und vor stationären Klinikaufenthalten als frühe Intervention Personen mit subklinischer als auch volldiagnostizierbarer Panikstörung angeboten werden. Das Training könnte so als präventives Angebot zur Verhinderung bzw. zur Verhinderung von Chronifizierung von Panikstörung und Agoraphobie beitragen. In den Behandelleitlinien

von Ländern, wie die Niederlande oder Großbritannien, wird dieses gestufte Vorgehen zur Behandlung von Panikstörung und Agoraphobie bereits empfohlen (NICE, 2011; van Balkom et al., 2013). Auch in Deutschland fordert die Bundespsychotherapeutenkammer eine Kostenübernahme solcher evidenzbasierten Online-Präventionsangebote durch die Krankenkassen (Bundespsychotherapeutenkammer, 2017).

### GET.ON Panik als face-to-face Ergänzung

Ein weiteres Anwendungsszenario ist die Einbettung des hybriden Online-Trainings – oder auch nur der GET.ON Panik App – in face-to-face Behandlungen im Rahmen der psychotherapeutischen Versorgung. Vorteile einer solchen *blended* Trainingsvariante sind die Einsparung bzw. effizientere Nutzung von therapeutische Ressourcen in Form von Zeit und Geld (Marks, Kenwright, McDonough, Whittaker, & Mataix-Cols, 2004). Auch TherapeutInnen stehen der Integration von Online-Elementen in die face-to-face Psychotherapie durchaus offen gegenüber (Bundespsychotherapeutenkammer, 2017; Titzler, Saruhanjan, Berking, Riper, & Ebert, 2018). In der Routineversorgung könnten sich die TherapeutInnen auf die Behandlung der komplexeren Symptomatologie (z. B. komorbide Depression oder Persönlichkeitsstörungen) konzentrieren, während weniger komplexe Paniksymptome an Online-Komponenten ausgelagert werden würden (Pittig, Kotter, & Hoyer, 2018). TherapeutIn und PatientIn könnten leicht EMA- und EMI-Daten austauschen, was zu einem kohärenten Behandlungsverlauf beitragen könnte.

### Qualitätskriterien als Voraussetzung für die Implementierung in die klinische Praxis

Bis jetzt werden internetbasierte Interventionen in Deutschland noch nicht durch die Kassen vergütet. Unerlässlich für eine erfolgreiche Implementation von Trainings wie GET.ON Panik als Präventions- oder Behandlungsangebot in die Regelversorgung, ist die vorherige Einführung von Qualitätskriterien und eines Gütesiegels, wie von der *Task Force E-Mental Health* der Berufsverbände DGPs und DGPPN gemeinsam gefordert (Klein et al., 2016). Qualitätskriterien bieten für alle involvierten Parteien, wie PatientInnen, TherapeutInnen und Versorgungsträger wie Krankenkassen eine Möglichkeit wirksame und sichere internetbasierte Interventionen zu identifizieren. Klein et al. (2018) schlugen insgesamt acht Kriterien vor, die von einem Nachweis der Evidenz durch mindestens eine randomisierte kontrollierte Studie über ausreichende Qualifikation des Interventionsentwicklerteams bis hin zur Sicherstellung einer hohen Datensicherheit reicht.

Dem Zeitgeist entsprechend haben immer mehr Personen die Präferenz niedrigschwellige mobile Hilfsangebote zu nutzen. Ohne Schwierigkeiten treffen sie bei ihrer Suche in den gängigen App-Stores auf ein umfangreiches Angebot, das Abhilfe bei allerlei Beschwerden verspricht. Jedoch kann folgendes Dilemma konstatiert werden: Die meisten Apps in den Stores sind nicht evaluiert. Gleichzeitig sind evaluierte Apps in der Routine häufig nicht frei zugänglich für die Hilfesuchenden. Die App-Märkte sind derzeit nur schwammig reglementiert und kontrolliert, und das Fatale dabei ist, dass es an Transparenz darüber fehlt. Für Betroffene ist es nur schwer möglich, ein seriöses, wirksames von einem unseriösen, nicht wirksamen Angebot zu unterscheiden. So besteht in Bezug auf die Qualitätssicherung von M-Health Apps ebenfalls zwingender Handlungsbedarf, um zum einen den VerbraucherInnenbedürfnissen gerecht zu werden und zum anderen für mehr Sicherheit auf dem unübersichtlichen App-Markt zu sorgen. Da der Schutz der Gesundheit von Betroffenen nicht den Prinzipien des (nahezu) freien Marktes unterliegen sollte, ist es wichtig, dass verschiedene Akteure des Gesundheitssystems, wie Krankenkassen, Berufsverbände, WissenschaftlerInnen und VertreterInnen politischer Instanzen in den Prozess der Qualitätssicherung von Gesundheits-Apps involviert werden. Daran anknüpfend sind Forderungen nach etwa einem hohen Krisenmanagement Standard oder sicherem Datenaustausch (Singh et al., 2016). Eine Zertifizierung des GET.ON Panik Trainings sowie der GET.ON Panik App nach vorher festgelegten Kriterien ist anstrebenswert, damit eine hohe Qualität und Sicherheit in der Nutzung sowie die transparente Aufklärung darüber gewährleistet werden kann.

**Implikationen für die Forschung**

Je mehr die Intervention untersucht ist, desto besser weiß man wie, warum, für wen und für wen gerade nicht sie wirkt. Die Evidenz des Online-Trainings sollte darum durch weitere Forschung gesichert werden. In diesem Zusammenhang werden folgende Forschungsfragen aufgeworfen:

***Welchen Mehrwert hat das hybride Format gegenüber anderen Trainingsformaten?***

Das hybride Online-Training GET.ON Panik zeigte in den durchgeführten Studien eine mittlere bis starke Wirksamkeit, allgemein gute Adhärenzraten, sowie eine hohe Akzeptanz der integrierten Smartphone-App. Die Vermutung liegt nahe, dass der innovative Ansatz des hybriden Trainingsformates einen wichtigen Beitrag zu den durchweg guten Studienergebnissen geleistet hat. Der spezifische Beitrag des Trainingsformates wurde in

dieser Arbeit jedoch nicht empirisch untersucht. In zukünftigen Vergleichsstudien soll darum der hybride Trainingsansatz gegen aktive Kontrollgruppen getestet werden. GET.ON Panik sollte in den Formaten browserbasiertes Training, *stand-alone* Panik-App und als hybrides Trainingsformat gegeneinander getestet werden. Die Verwendung einer *Dismantling*-Strategie (Basham, 1986) könnte dazu beitragen, den Beitrag des spezifischen Trainingsformats zur Wirksamkeit zu identifizieren.

### *Welche Prädiktoren, Mediatoren und Moderatoren haben Einfluss auf den Trainingserfolg?*

Zur Klärung der Wirksamkeit stellt sich zudem die Frage, welche weiteren Faktoren den Effekt des Trainings moderiert haben könnten. Um zu zeigen für welche Personengruppen das Training besonders indiziert ist, sollten zukünftige Studien entsprechend gepowered sein, um Mediatoren- und Moderatorenanalysen einschließen zu können. In einer 2012 publizierten Metaanalyse verglichen Haug et al. den Effekt von Selbsthilfe-Trainings für Angststörungen mit verschiedene Kontrollgruppen und fanden, dass in Studien mit einem geringeren Frauenanteil bessere Effekte erzielten wurden als in Studien mit höherem Frauenanteil, unter der Voraussetzung, dass Selbsthilfe gegen eine *face-to-face Treatment-as-usual* Bedingung getestet wurde. Dieser Befund deutet darauf hin, dass Männer mehr von internetbasierten Interventionen profitieren könnten als Frauen. Da in den vorliegenden Studien die Beobachtung gemacht wurde, dass der Männeranteil in den Studienpopulationen überdurchschnittlich groß war, wäre es für Folgestudien interessant zu schauen, ob Männer besser von dem Training profitieren können als Frauen. In einer anderen Studie (Cammin-Nowak et al., 2013) konnte nachgewiesen werden, dass sich *Hausaufgabencompliance* positiv auf die Symptomverbesserung auswirken kann – ein besonders starker Zusammenhang konnte bei in-vivo Expositionen gefunden werden. Auch bei GET.ON Panik wäre es interessant zu schauen, ob die Personen, die häufiger und intensiver in-vivo Expositionen durchführen, besser von dem Training profitieren könnten als die Personen, die dies weniger täten.

### *Ist die App auch in einem Blended-Training Format wirksam?*

In dieser Arbeit konnte gezeigt werden, dass die Kombination von einer mobilen Applikation mit einem browserbasierten Online-Training zur Behandlung von Panikstörung wirksam sein kann. Da die GET.ON Panik App Funktionen übernimmt, die im Alltag der KlientIn benötigt werden, nämlich das Symptom-Monitoring sowie Expositionsübungen, erscheint es ebenfalls vielversprechend, die GET.ON Panik App mit bestehenden face-to-

face Ansätzen zu verknüpfen und sie beispielsweise im Rahmen einer Psychotherapie einzusetzen und zu evaluieren.

### *Welche Rolle spielen unterschiedliche Guidance-Intensitäten?*

In den vorliegenden Studien in Kapitel 2 und 4 wurden die Intervention mit Unterstützung (*Guidance*) von geschulten PsychologInnen angeboten. Der Kontakt fand über ein schriftliches Feedback statt, das zu jeder Trainingslektion gegeben wurde und eine veranschlagte Zeit von etwa 30 Minuten umfasste. Im Zuge der Kosteneffektivität und der späteren Dissemination des Trainings ist der Umfang der Guidance hoch relevant. Domhardt, Steubl und Baumeister (2018) gingen in einer Metaanalyse der Frage nach, ob und in welchem Maße Guidance zum Trainingserfolg von internet- und mobilbasierten Interventionen bei Angsterkrankungen beiträgt. Sie fanden heraus, dass Interventionen, die durch eine intensive Unterstützung von einem Therapeuten angeboten wurden, wirksamer sind als Interventionen, die vollständig unbegleitet durchlaufen wurden. Dieser Effekt konnte im Vergleich von intensiver Unterstützung mit minimaler Unterstützung, die hauptsächlich auf den technischen Support fokussierte, nicht mehr hergestellt werden – hier scheint die Intensität der Begleitung keine Rolle mehr zu spielen. Auch das Qualifikationsniveau der begleitenden Coaches war im Allgemeinen irrelevant. Weitere Studien sollten die Auswirkungen der Intensität der Guidance innerhalb von GET.ON Panik untersuchen. Interessant wäre in diesem Kontext auch die Frage, ob Funktionen der App, einen Teil der Therapeuten-Unterstützung ersetzen kann, sowie es Ivanova et al. (2016) schlussfolgerten.

### *Wirkt das Training auch über längere Erhebungszeiträume?*

In der in Kapitel 4 beschriebenen randomisierten kontrollierten Studie wurde bei den meisten Ergebnissen die größten Verbesserungen bei den Nachuntersuchungen nach 3 und 6 Monaten beobachtet. Auch bei vorherigen Studien konnte stabile Zwischengruppen-Effekte über 1 Jahr (Carlbring et al., 2005, 2006; B. Klein, Richards, & Austin, 2006a), sowie im prä-post Vergleich sogar über 3 Jahre hinweg (Ruwaard, Broeksteeg, Schrieken, Emmelkamp, & Lange, 2010) gefunden werden. Da angenommen wird, dass mobile Komponenten ein besonders alltagsnahes Trainieren ermöglichen, sollten zukünftige Studien Messzeitpunkte von mehr als 6 Monaten umfassen, um die langfristige Wirksamkeit hybrider Interventionen bei Panikstörung bewerten zu können.

### Ist GET.ON Panik kosteneffektiv?

Panikstörung ist eine kostenintensive Erkrankung. Darum ist eine potentielle Kosteneffektivität der Intervention aus Arbeitgeberperspektive sowie aus gesamtgesellschaftlicher Sicht von besonderem Interesse. Bislang wurden Messungen zur Kosteneffektivität von (Online-)Selbsthilfetrainings bei Panikstörung nur in einer sehr geringen Anzahl an Studien durchgeführt (Batelaan, De Graaf, Van Balkom, Vollebergh, & Beekman, 2007; Ophuis, Lokkerbol, Hiligsmann, & Evers, 2018). Ophuis et al. (2018) konnten zeigen, dass eine internetbasierte Intervention für Personen mit subklinischen Paniksymptomen potentiell kosteneffektiv ist, Batelaan et al. (2007) fanden ähnliche Ergebnisse für ein *offline* Selbsthilfe-Training bei ebenfalls subklinischer Panikstörung. Für eine hybrides Format liegt solch eine Kosteneffektivitätsanalyse jedoch noch nicht vor. Wie im Studienprotokoll in Kapitel 3 beschrieben, wurden bei der Konzeption der Wirksamkeitsstudie zu GET.ON Panik die jeweiligen Messinstrumente einbezogen, um die Kostenwirksamkeit und den Kosten-Nutzen der Intervention aus gesellschaftlicher Sicht beurteilen zu können. Da die Daten zur Kosteneffektivität von GET.ON Panik von großer praktischer Bedeutung sind, werden sie zu gegebener Zeit analysiert und veröffentlicht.

### Verursacht GET.ON Panik negative Effekte?

Trotz einer hohen Wirksamkeit, kann es sein, dass die Intervention Schäden verursacht (Rozental et al., 2014). Die Erfassung von ungewollten Nebenwirkungen und negativen Effekten, im Sinne einer Symptomverschlechterung, bleibt in vielen E-Mental Health Studien meist noch unberücksichtigt. In der vorliegenden Wirksamkeitsstudie wurde der INEP Fragebogen zur Erfassung von negativen Effekten von Psychotherapie (Ladwig, Rief, & Nestoriuc, 2014) zwar erhoben, jedoch an anderer Stelle ausgewertet. In weiteren Studien ist es darum wichtig, den Fokus von Wirksamkeit und Adhärenz auch auf potentielle negative Effekte zu erweitern und mögliche Schäden systematisch zu erfassen, um daraus Implikationen für den Umgang mit Betroffenen und für die weitere Trainingsentwicklung abzuleiten.

### Ist GET.ON Panik unter Routinebedingungen wirksam?

Die Frage, ob die Intervention GET.ON Panik auch unter Routinebedingungen wirksam ist, ist letztendlich noch unbeantwortet. Aus diesem Grund sollten neben den bereits genannten Forschungsfragen auch Implementierungsstudien (vgl. Nordgreen, Gjestad, Andersson,

Carlbring, & Havik, 2018; Titzler, Saruhanjan, Berking, Riper, & Ebert, 2018) durchgeführt werden, um zu untersuchen, ob der Transfer in die Routine gelingt.

Aktuell wird GET.ON Panik im Rahmen eines Präventionsprojektes der Sozialversicherung für Landwirtschaft, Försterei und Gartenbau (SVLFG) bei der Zielgruppe der Grünen Berufe (Heber et al., 2018) eingesetzt und hinsichtlich Implementierbarkeit evaluiert.

**Technologische Erweiterungen der GET.ON Panik App**

Innovative Forschungsfragen bedingen eine innovative Weiterentwicklung der Technik. Die nachfolgenden Punkte sollten bei der weiteren Entwicklung der Smartphone-App berücksichtigt werden.

*Automatische Synchronisation zwischen Plattform und App*

Per Definition wird ein hybrides Training auf zwei Geräten genutzt: zum einen auf dem Smartphone und zum anderen auf dem Laptop- oder Desktop-PC. Aus Gründen der Benutzerfreundlichkeit ist eine automatische Synchronisation der eingegebenen Daten zwischen der mobilen App und dem browserbasierten Training wünschenswert, um doppelte Eingaben auf beiden Geräten zu vermeiden und stattdessen ein kontinuierlichen Trainingsprozess zu ermöglichen.

*Nutzen der Sprachfunktion*

Da einige Teilnehmende von Schwierigkeiten berichteten, die App in hohem Erregungszustand zu bedienen, wie es beispielsweise während Panikattacken oder Expositionen üblich ist, sollte die Bedienbarkeit der App für die Teilnehmenden erleichtert werden. Die Dateneingabe sollte ebenfalls mit dem integrierten Sprachrekorder erfolgen können, welche *Sprache-zu-Text* überträgt.

*Nutzen von Sensoren*

Darüber hinaus lässt die aktuelle Version der App das Potenzial integrierter Kontextsensoren noch unbeachtet. Für die langfristige Entwicklung der App wäre es sinnvoll, GPS-Daten für intelligente kontextsensitive Expositionsaufgaben zu verwenden. Die betroffene Person würde beispielsweise durch eine App-Benachrichtigung informiert, wenn sich in der Nähe eines zuvor definierten angstauslösenden Ortes befindet, wie etwa ein Einkaufszentrum oder ein hoher Turm. Daraufhin würde sie dazu eingeladen werden, eine Expositionsaufgabe durchzuführen.

### Gamifizierung

*Serious Games* (Computerspiele, die einem ernsten Zweck entsprechen) und *Gamification* (Spielelemente in nicht-spielerischen Kontexten) haben das Potenzial, Wirkung und Adhärenz von internetbasierten Interventionen weiter zu erhöhen, indem sie die Reichweite auch auf bisher unerreichte Personen ausweiten und Teilnehmende aktiv in das Training einbinden (Brown et al., 2016; Fleming et al., 2017; Lau, Smit, Fleming, & Riper, 2017). Eine Gamifizierung der GET.ON Panik App, beispielsweise in einem kontextsensitiven „Expositionsspiel" – wie oben beschrieben –, könnte die Motivation der Teilnehmenden weiter fördern. Bei erfolgreicher Bewältigung der gestellten Aufgabe würde es eine Belohnung in Form von Punkten geben. Ziel des Spieles wäre es, möglichst viele Punkte zu sammeln.

### Nutzen von künstlicher Intelligenz

Der Einsatz von künstlicher Intelligenz bietet großes Potenzial für die Diagnostik und Behandlung von psychischen Erkrankungen. *Chatbots* als therapeutische Unterstützung (Fulmer, Joerin, Gentile, Lakerink, & Rauws, 2018), Rückschlüsse über die Stimmung aufgrund des *Touch*-Verhaltens auf dem Smartphone-Display (Heraz & Clynes, 2018) oder Änderungen im Kommunikationsmusters zur Detektion potentieller Rückfalle (Beiwinkel et al., 2016) sind nur einige von vielen möglichen Einsatzgebieten. Als Zukunftsvision ist die Integration künstlicher Intelligenz und *machine-learning* im Rahmen von E- und insbesondere M-Mental Health Interventionen wie dieser ebenfalls denkbar. Beispielsweise könnte eine Weiterentwicklung der GET.ON Panik App ein automatisiertes Erkennen von Vermeidungsverhalten durch Stimm- und Bewegungsmuster beinhalten. Bei regelmäßiger Nutzung würde die App stets besser ‚lernen', welche Situation ihre NutzerIn meidet. Entsprechend könnten EMI-Übungen zur Gegensteuerung angeboten werden.

## Fazit

Die in dem Rahmen dieser Dissertation entstandenen Studien liefern einen Beitrag für das wachsende Forschungsfeld E- und M-Mental Health. Die vorliegende Arbeit zeigt, dass ein hybrides Online-Training, bei dem ein internetbasiertes Training mit einer mobilen Applikation ergänzt wurde, dazu beitragen kann, psychische Beschwerden bei Personen, die unter Panikstörung und Agoraphobie leiden, zu reduzieren. Die Effekte dieses Trainings auf die Reduktion von Paniksymptomen waren statistisch wie klinisch zum Postzeitpunkt

moderat ausgeprägt, stiegen aber über einen Zeitraum von 6 Monaten hinweg an und bildeten starke Effektstärken ab. Zudem wiesen Personen, die an dem Training teilgenommen haben, nach 6 Monaten eine signifikant höhere Lebensqualität sowie signifikant weniger depressive Symptome auf als die Wartelisten-Kontrollgruppe. Des Weiteren konnte gezeigt werden, dass die Integration mobiler Komponenten viele Vorteile in Bezug auf Adhärenz, Akzeptanz und Machbarkeit von Selbstmonitoring und Selbstexpositionen im Rahmen von internetbasierten Intervention aufgewiesen hat. Jedoch als valides EMA-Instrument in den beiden durchgeführten Studien nicht eingesetzt werden konnte. In zukünftigen Studien soll getestet werden, ob der hybride Ansatz des GET.ON Panik Trainings dem eines anderen Trainingsformates, wie einer rein browserbasierten Version oder auch einer ausschließlich mobil angebotenen Version des Trainings, überlegen ist. Die Durchführung einer Dismantling-Studie könnte beispielsweise helfen, den Beitrag des spezifischen Trainingsformats, zur Wirksamkeit sowie zur Adhärenz von internetbasierter kognitiver Verhaltenstherapie genauer zu identifizieren.

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## About the author

Lara Ebenfeld was born on July 25, 1984 in Bielefeld, Germany. After receiving her high school diploma, she enrolled in the study of psychology at the Radboud University in Nijmegen, the Netherlands. In 2010, she graduated with honors as a Master of Science, and in 2011 she took on the position of research assistant at the Leuphana University in Lüneburg. Here she became involved in the project "Health.Training Online" – a large research project funded by the European Union – and worked on innovative treatment options, for instance the use of mobile technology in the context of psychological interventions. As part of an international interdisciplinary team she developed an online training, and a smartphone app for panic disorder and agoraphobia. Her PhD thesis "Development and evaluation of a hybrid online training for panic disorder and agoraphobia" was also linked to this project. Lara Ebenfeld currently lives in Hamburg and works in the area of e-mental health.

## Über die Autorin

Lara Ebenfeld wurde am 25. Juli 1984 in Bielefeld geboren. Nach dem Abitur nahm sie ihr Psychologiestudium an der Radboud Universiteit in Nijmegen in den Niederlanden auf, welches sie 2010 mit dem Master of Science mit Auszeichnung abschloss. Eine Anstellung als wissenschaftliche Mitarbeiterin führte sie 2011 an die Leuphana Universität nach Lüneburg. Dort beschäftigte sie sich im Projekt „Gesundheits.Training Online", einem großen von der Europäischen Union geförderten Forschungsprojekt, mit innovativen Behandlungsmöglichkeiten, wie etwa den Einsatz mobiler Technologie im Rahmen von psychologischen Interventionen. So entwickelte sie in einem internationalen interdisziplinären Team ein Online-Training sowie eine Smartphone-App für Panikstörung und Agoraphobie. Auch ihr Promotionsvorhaben „Entwicklung und Evaluation eines hybriden Online-Trainings bei Panikstörung und Agoraphobie" war an dieses Forschungsprojekt angeknüpft. Aktuell lebt Lara Ebenfeld in Hamburg und arbeitet im Bereich E-Mental Health.