Help for insomnia from the app store? A standardized rating of mobile health applications claiming to target insomnia

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Summary
A large number of mobile health applications claiming to target insomnia are available in commercial app stores. However, limited information on the quality of these mobile health applications exists. The present study aimed to systematically search the European Google Play and Apple App Store for mobile health applications targeting insomnia, and evaluate the quality, content, evidence base and potential therapeutic benefit. Eligible mobile health applications were evaluated by two independent reviewers using the Mobile Application Rating Scale-German, which ranges from 1 – inadequate to 5 – excellent. Of 2236 identified mobile health applications, 53 were included in this study. Most mobile health applications (68%) had a moderate overall quality. Concerning the four main subscales of the Mobile Application Rating Scale-German, functionality was rated highest (M = 4.01, SD = 0.52), followed by information quality (M = 3.49, SD = 0.72), aesthetics (M = 3.31, SD = 1.04) and engagement (M = 3.02, SD = 1.03). While scientific evidence was identified for 10 mobile health applications (19%), only one study employed a randomized controlled design. Fifty mobile health applications featured sleep hygiene/psychoeducation (94%), 27 cognitive therapy (51%), 26 relaxation methods (49%), 24 stimulus control (45%), 16 sleep restriction (30%) and 24 sleep diaries (45%). Mobile health applications may have the potential to improve the care of insomnia. Yet, data on the effectiveness of mobile health applications are scarce, and this study indicates a large variance in the quality of the mobile health applications. Thus, independent information platforms are needed to provide healthcare seekers and providers with reliable information on the quality and content of mobile health applications.

KEYWORDS
apps, mHealth, mobile health, sleep disorder, systematic investigation

1 INTRODUCTION

The treatment of insomnia is highly relevant, given the high prevalence and burden of disease, and as insomnia is a risk factor for other mental health disorders and somatic diseases (Hertenstein et al., 2019; Morin et al., 2015; Sofi et al., 2014). National and international clinical guidelines recommend Cognitive Behavioural Therapy for Insomnia (CBT-I) as the first-line treatment (Riemann et al., 2017).
Despite CBT-I being a highly effective treatment, it is only provided to a small proportion of patients suffering from insomnia, given its limited availability and accessibility (Koffel et al., 2018a). Given the limited availability of CBT-I and the emerging market of mobile health applications (MHAs), patients suffering from insomnia or their healthcare providers may refer to the commercial app stores. Indeed, MHAs seem like a promising low-threshold approach for providing digitalized CBT-I, given the ubiquity of smartphones and the possibility to access MHAs independent of place and time (Hussain et al., 2015; Uyumaz et al., 2021). Moreover, MHAs may help to overcome shortcomings of traditional on-site therapy, particularly if long waiting times for on-site therapy are to be expected or if patients fear being stigmatized for seeking on-site therapy (Andrade et al., 2014; Ebert et al., 2018; Hussain et al., 2015).

Notwithstanding the potential benefits of MHAs, the free availability of MHA also harbors potential risks. While many app store descriptions make claims regarding the effectiveness of MHAs, the majority of MHAs available on the app market yield no direct scientific evidence (Larsen et al., 2019; Terhorst et al., 2020), and the effectiveness of already examined MHAs seems less established compared with the well-established effectiveness of Internet-based interventions (Weisel et al., 2019). In the case of insomnia, the efficacy of Internet-based interventions is well studied (Soh et al., 2020; Zachariae et al., 2016), whereas the evidence for MHAs delivering CBT-I is limited. As no standards for MHAs available in the app stores exist, the content of MHAs may not be guideline compliant, and MHAs of low quality may lead to the dissemination of false information, mistreatment or side-effects (Albrecht, 2016; Huckvale et al., 2020). Moreover, issues regarding data protection, privacy and the quality of the content of MHAs are of major concern (Hussain et al., 2015). Thus, selecting a suitable MHA may be a major challenge for both healthcare seekers and providers.

To our knowledge, two evaluations of commercially available MHAs targeting insomnia have been conducted (Leigh et al., 2017; Yu et al., 2019). Leigh et al. (2017) evaluated data security, clinical effectiveness and user engagement using the ORCHA-24 framework of 19 Android MHAs available in the British Google Play Store identified by the single search term “insomnia”. Yu et al. (2019) evaluated the quality of 12 MHAs available in the American Apple App and Google Play Store using the Mobile Application Rating Scale (MARS; Stoyanov et al., 2015) identified by the three search terms “insomnia”, “insomnia treatment” and “sleep treatment.” A more complex search strategy may be necessary to identify all relevant MHAs available in the Apple App and Google Play Stores, as MHAs may have been indexed with other keywords in the app stores. Moreover, given the high volatility of the app market (Larsen et al., 2016), the two aforementioned evaluations might be already outdated. Therefore, the primary aim of the study was to provide an updated overview of the quality domains that are likely to influence the effectiveness of MHAs (assessed using the MARS-German [MARS-G]) of MHAs targeting insomnia that are currently available in the Google Play and Apple App Stores. The secondary aim of the study was a description of the content, evidence base and potential therapeutic benefit of these MHAs.

### Table 1: Eligibility criteria for inclusion

| Inclusion criteria | Exclusion criteria |
|--------------------|-------------------|
| **Level 1:** Before downloading the MHA; using titles and descriptions in the app store | **Only intended for healthcare providers** |
| - Target group: adults suffering from symptoms of insomnia | **Only intended for relatives of persons suffering from insomnia** |
| - Useful for the psychotherapeutic treatment of insomnia according to the description | **Primarily intended for other disorders than insomnia** |
| - Title or description includes the word “insomnia” or “sleep disorder” | **Needs another device (e.g. smartwatch) to function** |
| - MHA is available in English, German or French | **Only available for tablets** |
| - Fully functional to allow assessment | **Only functional in blended-care models** |

| **Level 2:** After downloading the MHA; using the content of the MHAs | **Features only an alarm clock or sleep-tracking functions that measure sleep through sensors** |
| - Features at least one of the following CBT-I components: sleep hygiene/psycho-education, stimulus control, sleep restriction, cognitive therapy | **Features only relaxing music, noise or bedtime stories** |
| - Or features a sleep diary or an assessment of sleep disturbances | **eBooks** |
| - Fully functional to allow assessment | **Duplicate** |
| - Part of the content is only accessible via other modalities (e.g. browser-based intervention) | **Not functional to a degree that allows assessment** |

 footnote="Sleep hygiene education and psychoeducation were evaluated as one treatment component in this study. CBT-I, Cognitive Behavioural Therapy for Insomnia; MHA, mobile health application."

### 2 | METHODS

#### 2.1 | Search strategy and eligibility criteria

A web crawler (Stach et al., 2020) was used to systematically screen the European Apple App and Google Play Store with insomnia-related search terms. The validity of this procedure has been demonstrated in previous studies (Portenhauser et al., 2021; Schultchen et al., 2020; Terhorst et al., 2018, 2021). Search terms and eligibility criteria were chosen with the intention that included MHAs are likely to represent the MHAs with which healthcare seekers and providers are
confronted with when they search the app stores for suitable MHAs. Table S1 summarizes the used search terms. The search was conducted from 18 September to 23 September 2020. In addition, systematic literature reviews (Aji et al., 2020; Weisel et al., 2019) as well as published evaluations of MHAs targeting insomnia available in the app stores (Leigh et al., 2017; Yu et al., 2019) were screened for other relevant MHAs. All identified MHAs were listed in a central database and duplicates were removed. Identified MHAs were systematically screened in a two-level process using pre-defined criteria as outlined in Table 1. While sleep hygiene educations/psychoeducation and sleep diaries are not effective face-to-face standalone interventions, we decided to still include MHAs that featured only these components, as they may be particularly interesting for therapists in blended-care models. MHAs were only included if they were functional to a degree that assessment was possible. Eventual technical problems were verified on two separate devices. For the evaluation of the Android MHAs a Huawei P10 lite (Modell WAS-LSX1A) was used, and for the iOS MHAs an Apple iPhone 6s (Modell NNOX2ZD/A) was used.

2.2 | Data collection process

Each MHA was rated by two independent reviewers with a degree in psychology (JR, LS, JW and KB) using the MARS-G (Messner et al., 2020). Before the rating, the reviewers received standardized publicly accessible online training (https://www.youtube.com/watch?v=5vwMiCWC05c). Each MHA was explored and used for at least 15 min to examine functionality, content and quality. The quality rating was carried out on a database specifically developed for these ratings (Stach et al., 2020). If an MHA was available for both operating systems (i.e. iOS and Android), the MHA was rated for both operating systems individually. Author LSS was consulted if ratings of an item differed by 2 points or more, and these discrepancies were resolved by discussion. The overall quality rating showed an excellent level of interrater reliability between the two reviews (two-way mixed for agreement intraclass correlation coefficient [ICC] = 0.92; 95% confidence interval 0.91–0.93), and the internal consistencies were estimated to be good to excellent for the subscales (Omega = 0.86–0.97), and excellent (Omega = 0.96) for the overall ratings.

2.3 | General characteristics

The following descriptive and technical information were extracted using the classification page of the MARS-G: (1) MHA name; (2) platform (i.e. Apple App or Google Play Store); (3) annual cost in € (i.e. if the MHA included a monthly subscription the annual cost was calculated); (4) user star ratings; and (5) privacy and security features. The assessment of privacy and security features occurred on a descriptive level (e.g. availability of privacy policy, imprint, usage of passwords, and logins). All features were assessed based on the downloaded MHAs, and only information disclosed within the MHA, its website or its description in the app stores was investigated.

2.4 | App quality rating using the MARS-G and scientific evidence

While the mechanisms of change are not sufficiently studied for MHAs, it can be assumed that additional factors besides the content influence the effectiveness of an MHA. For example, user engagement and persuasive design appear to have a major influence on the retention of MHAs outside the research context (Baumel et al., 2019). Thus, MHA quality is likely to be a multidimensional construct (Nouri et al., 2018). The MARS is a validated and widely used multidimensional measure for the quality assessment of MHAs (Stoyanov et al., 2015; Terhorst et al., 2020), which has been developed by a multidisciplinary expert team. Its psychometric properties have been investigated in an international validation study that included over 1200 MHAs from 15 indication areas, and the objectivity (ICC = 0.82), reliability (Omega = 0.79–0.93), construct validity (root mean square error of approximation = 0.074, Tucker-Lewis index = 0.922, confirmatory fit index = 0.940, standardized root mean square residual = 0.059) and concurrent validity were all good to excellent (Terhorst et al., 2020). The generic formulation of the MARS items allows for an adaption of the ratings to the targeted indication area. While the MARS has been previously applied to the domain of insomnia (Yu et al., 2019), it must be noted that the MARS has not been validated for MHAs targeting insomnia. For this study, we have used the German version of the MARS (MARS-G) (Messner et al., 2020). The quality rating of the MARS-G is based on a 5-point scale (i.e. 1 = inadequate, 2 = poor, 3 = acceptable, 4 = good and 5 = excellent), and includes four main subscales: (a) engagement (5 items: entertainment, interest, customization, interactivity, target group); (b) functionality (4 items: performance, usability, navigation, gestural design); (c) aesthetics (3 items: layout, graphics, visual appeal); (d) information quality (7 items: accuracy of app description, goals, quality of information, quantity of information, quality of visual information, credibility, evidence base; Messner et al., 2020). The information quality was evaluated regarding the goal that was defined in the app store description, which may limit the comparability of MHAs with varying goals. For example, if the goal in the app store description was to educate users about insomnia, the focus of the information quality evaluation was the quality of the psychoeducation. The item evidence base was used to assess whether the MHAs have been scientifically evaluated. This item was investigated by searching the MHA name in Google Scholar, the developers’ or providers’ websites, as well as systematic literature reviews of MHAs (Aji et al., 2020; Weisel et al., 2019) for existing studies.

2.5 | Treatment components, potential therapeutic benefit and potential therapeutic safety

To examine the compliance with guideline recommendations, it was assessed if the MHAs included the following treatment components: (a) sleep hygiene/psychoeducation; (b) stimulus control; (c) sleep restriction; (d) cognitive therapy; (e) relaxation methods. Moreover, it was
assessed if MHAs featured sleep diaries. Assessment of the featured treatment components occurred on a descriptive level. Potential therapeutic gain and potential therapeutic safety were rated using the additional subscale therapeutic gain of the MARS-G (Messner et al., 2020). Therapeutic gain evaluates the benefit for the patient (i.e. to which extent could the MHA support the user in the treatment of his or her symptoms), benefit to the therapist (i.e. to which extent may the MHA help to optimize the therapy), the transferability into a routine setting (i.e. has the MHA been tested on patients and under conditions that are representative of routine psychotherapy setting), and potential therapeutic safety (i.e. is there a risk for adverse effects due to misleading or wrong information or incorrect recommendations). We extended the criteria defined by this item by evaluating if MHAs formulated suspected or definitive diagnoses, and if diagnoses were paired with the recommendation to consult healthcare providers. Moreover, for MHAs featuring sleep restriction, it was assessed if MHAs included information on contraindications (e.g. sleep-disordered breathing or epilepsy; Spielman et al., 2011) and possible negative effects of sleep restriction. Additionally, it was assessed if information on differential diagnoses was provided, if app store descriptions included disclaimers that the MHA does not substitute treatment, and if information on finding on-site help was provided.

2.6 | Data analyses

The ratings of the two independent reviews were averaged for all calculations. For the four main subscales, the average of the respective items was taken, and for the overall quality the total score was calculated from the four main subscales of the MARS-G (Messner et al., 2020). Mean scores (M) and standard deviations (SD) were calculated for the overall quality and the MARS-G main subscales. Moreover, the MARS-G overall rating and the ratings of the MARS-G subscales were categorized as low (i.e. rating of less than 2.5), moderate (i.e. rating between 2.5 and 4) and high (i.e. rating of 4 and higher).

Visual inspection of the histograms and Shapiro–Wilk normality tests indicated a non-normal distribution of the data. Hence, Wilcoxon rank-sum tests with continuity correction were used to test whether the MHAs from the Apple App and Google Play Store differed regarding their MARS-G overall ratings, and if MHAs with a free or non-free basic version differed in their MARS-G overall rating. For all analyses, an alpha level of 5% was defined. All statistical analyses were performed using R. For an illustration of details of potentially helpful MHAs targeting insomnia, MHAs that received a rating of 4 or higher for both the overall quality and the additional subscale therapeutic gain will be described in detail in the supplemental material (Table S2).

3 | RESULTS

3.1 | Selection process

Figure 1 displays the MHA selection process and provides an overview of the reasons for exclusion. From 2236 identified MHAs, 53 MHAs (2%) were included in this study. Thirty-seven MHAs were available in the Google Play Store and 16 MHAs in the App Store.

3.2 | General characteristics

The general characteristics of the included MHAs are summarized in Table 2. The majority of the MHAs (85%) included a free basic version. The annual cost of the eight MHAs requiring payment for the basic version ranged from €1.57 to €10.99 (M = 5.24€, SD = 3.89€). Ten MHAs included an extended version (i.e. to access all content of the MHAs), with the annual cost ranging between €5.49 and €1920.00 (€ (M = 225.10€, SD = 596.68€, Median = 35.99€). The MHAs that were rated by users in the app stores (n = 20) had an average user star rating of M = 3.85 (SD = 0.80). The MHAs included on average four security and privacy measures (M = 3.62, SD = 1.97). Most frequently, a contact or imprint was provided (96%), while only seven MHAs (13%) included an emergency function. Tables 3 and 4 detail the security and privacy measures per MHA.

3.3 | App quality rating using the MARS-G and scientific evidence

The overall quality of the MHAs conceptualized as the mean of the four subscales of the MARS-G was moderate (M = 3.46, SD = 0.71); 14 MHAs received a high-quality rating, 36 a rating of moderate quality, and three MHAs a rating of low quality. Concerning the four main subscales of the MARS-G, functionality was rated highest (M = 4.01, SD = 0.52), followed by information quality (M = 3.49, SD = 0.72), aesthetics (M = 3.31, SD = 1.04) and engagement (M = 3.02, SD = 1.03). Table 5 summarizes the results of the MARS-G ratings, Tables 3 and 4 detail the MARS-G ratings per MHA, and Figure S1 provides a graphical representation of the overall quality ratings and the four main subscales of the MARS-G.

Two-sided Wilcoxon rank-sum tests indicated no significant difference (W = 388.5, p > 0.05) in the overall quality between MHAs of the Apple App Store (M = 3.72, SD = 0.71) and MHAs of the Google Play Store (M = 3.34, SD = 0.69), and no significant difference (W = 234.5, p > 0.05) in the overall quality of MHAs with a free (M = 3.53, SD = 0.73) and non-free basic version (M = 3.07, SD = 0.44).

We were able to identify scientific evidence for 10 MHAs (19%). Yet, this evidence included only one randomized controlled pilot study that compared regular on-site CBT-I with a blended-care model that paired on-site CBT-I with the MHA “CBT-i Coach”, and results of this study yielded non-significant differences for insomnia severity (Koffel et al., 2018b). The other evidence included observational studies (Eyal et al., 2020; Harbison et al., 2018), a survey of clinicians (Kuhn et al., 2016), and a randomized controlled trial investigating the browser version of an MHA (Lorenz et al., 2019). Table 6 provides a summary of the evidence and the corresponding ratings for the item evidence base of the MARS-G.
3.4 Treatment components, potential therapeutic benefit and potential therapeutic safety

The majority of the MHAs included sleep hygiene/psychoeducation (n = 50, 94%). Almost half of the MHAs included a sleep diary (n = 24, 45%) and 26 MHAs (49%) included relaxation methods. Cognitive therapy (n = 27, 51%), stimulus control (n = 24, 45%) and sleep restriction (n = 16, 30.2%) were commonly featured in the MHAs. Moreover, 17 MHAs (32%) featured a combination of sleep hygiene/psychoeducation, behavioural therapy (i.e. sleep restriction or stimulus...
General characteristics of the reviewed MHAs

|                                | n     | MHAs (%) | M (SD) |
|--------------------------------|-------|----------|--------|
| App store/operating systema   |       |          |        |
| Apple App Store/iOS            | 16    | 30.2%    |        |
| Google Play Store/Android      | 37    | 69.8%    |        |
| Annual costs                   |       |          |        |
| Number and annual cost of     | 8     | 15.1%    | 5.24€  |
| MHAs requiring payment for the |       |          | (3.90€)|
| basic versionb                |       |          |        |
| Number and annual cost of     | 10    | 18.9%    | 225.10€|
| MHAs offering an extended     |       |          | (596.68€)|
| versionsc                      |       |          |        |
| User star ratings              |       |          |        |
| Apple App Store                |       |          |        |
| MHAs with rating and          | 5     | 31.3%    | 4.34   |
| respective user star rating   |       |          | (0.65) |
| Google Play Store              |       |          |        |
| MHAs with rating and          | 15    | 40.5%    | 3.68   |
| respective user star rating   |       |          | (0.79) |
| Security and privacyd         |       |          |        |
| Allows password use            | 19    | 35.8%    |        |
| Requires a login               | 14    | 26.4%    |        |
| Has a privacy statement        | 40    | 75.4%    |        |
| Requires active confirmation   | 20    | 37.7%    |        |
| of a consent form              |       |          |        |
| Information on how data are   | 37    | 69.8%    |        |
| handled                        |       |          |        |
| Contact/contact person/        | 51    | 96.2%    |        |
| imprint                        |       |          |        |
| Secure data transfer           | 17    | 32.1%    |        |
| Emergency functions available  | 7     | 13.2%    |        |
| Security strategies for mobile | 4     | 7.5%     |        |
| phone loss                     |       |          |        |

Eight MHAs, thus 16 in total, were available for both app stores.

The MHA “somnio” was classified as free of charge, as German users do not need to pay a fee if general care physicians or psychotherapists prescribe the MHA. However, the statutory health insurances have to pay 464,00€ per prescription.

Users have to pay a fee to access the full content of MHAs offering an extended version.

Multiple naming of different data protection precautions for one MHA is possible.

MHAs (%)

Table 2 provides a visualization of the additional MARS-G subscale therapeutic gain.

The item risks and side-effects indicated that 33 MHAs (62%) may be associated with risks (i.e. rating of less than 4). Fourteen MHAs included questionnaires to assess sleep disturbances. None of these MHAs assessing sleep disturbances provided a definitive diagnosis. Instead, seven MHAs indicated suspected diagnoses and advised users to consult healthcare providers. Information on contraindications of using the MHA (e.g. epilepsy, shift work) was provided by the MHAs “Insomnia Coach” (both operating systems) and “somnio” (both operating systems). Additionally, the MHAs “Insomnia Coach” (both operating systems) and “somnio” (both operating systems) included information on contraindications and/or possible adverse effects of using the MHA. Thus, only the MHAs “Insomnia Coach” (both operating systems) and “somnio” (both operating systems) of the 16 MHAs featuring sleep restriction included information on potential side-effects of using the MHA. The MHAs “Insomnia Coach” (both operating systems) and “somnio” (both operating systems) achieved a high rating (i.e. rating > 4) for the overall quality and the additional subscale therapeutic gain. Thus, these MHAs may be particularly relevant for the treatment of insomnia. Table S2 provides a detailed overview of these MHAs.

4 DISCUSSION

We systematically assessed the general characteristics, quality rating based on the MARS-G, evidence base, treatment components, potential therapeutic benefits and potential therapeutic safety of MHAs targeting insomnia available in the Google Play and Apple App stores. The screening process revealed a plethora of MHAs in the app stores. Given the large number of MHAs targeting insomnia that feature additional subscale therapeutic gain. Thus, these MHAs may be particularly relevant for the treatment of insomnia. Table S2 provides a detailed overview of these MHAs.

Twelve MHAs (23%) were categorized as potentially beneficial (i.e. rating of 4 or higher) for patients, and seven MHAs (13%) as potentially beneficial for therapists using the additional subscale therapeutic gain of the MARS-G. The ease of implementation in the routine care was rated as low (i.e. rating of less than 2.5) for 45 MHAs (85%).

Engagement was rated lowest of the four main subscales of the MARS-G (M = 3.02, SD = 1.03), and almost 40% of the rated MHAs were categorized as having a low level of engagement. This is a pattern that has been also found in investigations of MHAs targeting other mental health domains (Terhorst et al., 2020). Yet, user engagement might be an important countermeasure against low retention rates, which in turn appear to be a problem of MHAs in real-world settings (Baumeister et al., 2019). Thus, it may be advisable to employ features of smartphones that offer unique benefits to therapy (e.g. reminding functions and responsive sleep diaries), and persuasive design to foster user engagement and retention (Baumeister et al., 2019; Uyumaz et al., 2021).
| MHA name (developer)                        | Available on android | User star rating (n ratings) | Annual cost basic (extended) | Security features | Engagement | Functionality | Aesthetics | Information | Overall quality | Treatment components |
|--------------------------------------------|----------------------|-----------------------------|-----------------------------|------------------|-------------|---------------|------------|-------------|------------------|-----------------------|
| Somnio (mementor DE GmbH)                  | Yes                  | 4.2 (43)                   | Free (NA)                   | Pw,Log,Pri,IC,Info,Con,Mo | 5.00        | 4.50          | 5.00       | 4.36        | 4.71             | SHE,SC,SR,CT,RE,SD,MI |
| Sleep Cure: Smart Sleep Coach (SleepCure AB)| Yes                  | None                       | Free (35.99€)               | Pw,Pri,IC,Info,Con | 4.60        | 4.25          | 4.83       | 4.75        | 4.61             | SHE,SC,CT,RE,SD,MI |
| Insomnia Coach (US Department of Veterans Affairs) | Yes                  | 4 (12)                     | Free (NA)                   | Pri,IC,Info,Con,Em | 4.30        | 4.12          | 4.67       | 4.57        | 4.42             | SHE,SC,SR,CT,RE,SD,MI |
| Soutien psy avec Mon Sherpa (doctoconsult) | Yes                  | None                       | Free (NA)                   | Pw,Log,Pri,IC,Info,Con,Mo | 4.50        | 3.62          | 4.67       | 4.33        | 4.28             | SHE,CT,RE            |
| Sleepate. Balance Your Sleep. (Sleepate)   | Yes                  | None                       | Free (131.88€)              | Pw,Log,Pri,IC,Info,Con,Em | 4.20        | 4.25          | 4.50       | 4.00        | 4.24             | SHE,SC,CT,RE,SD,MI |
| Sleep School for Professionals (The Sleep School Ltd) | No                  | None                       | Free (NA)                   | Pw,Log,Pri,Con | 3.90        | 4.25          | 4.50       | 3.83        | 4.12             | SHE,CT,RE,MI        |
| Sleepedy (Sleepedy, Inc.)                  | No                   | None                       | Free (NA)                   | Pw,Pri,IC,Info,Con | 3.30        | 4.25          | 4.00       | 4.08        | 3.91             | SHE,SC,SR,CT,SD     |
| Sleep: Better Sleep with CBT (Learning 2 Sleep) | No                  | None                       | Free (NA)                   | Pw,Pri,IC,Info,Con | 3.50        | 4.50          | 4.00       | 3.58        | 3.90             | SHE,CT,RE,MI        |
| Sleep School for Insomnia (The Sleep School Ltd) | Yes                  | None                       | Free (37.99€)               | Pw,Log,Pri,Info,Con | 3.70        | 4.12          | 3.83       | 3.67        | 3.83             | SHE,CT,MI           |
| CBT-i Coach (US Department of Veterans Affairs) | Yes                  | 3.5 (56)                   | Free (NA)                   | Pri,IC,Info,Con,Em | 3.80        | 3.50          | 3.33       | 4.57        | 3.80             | SHE,SC,SR,CT,RE,SD,MI |
| Night Owl - Sleep Coach (Mindware Consulting, Inc) | Yes                  | None                       | 10.99€ (NA)                 | Pw,Log,Pri,Con | 3.00        | 3.75          | 3.17       | 3.57        | 3.37             | SHE,SC,CT,RE,SD,MI |
| Mieux dormir – Psychologies (Teach on Mars) | No                   | None                       | 5.49€ (NA)                  | Pri,Info,Con     | 2.90        | 3.62          | 3.83       | 2.92        | 3.32             | SHE,SC,CT,RE,MI     |
| Besser Ein- und Durchschlafen (Audiog GmbH) | No                   | None                       | 2.29€ (NA)                  | Con              | 2.20        | 4.62          | 3.17       | 3.25        | 3.31             | SHE,RE,MI           |
| Sleep Solution: Insomnia help (Tom McKay)  | No                   | 5 (2)                      | 2.30€ (NA)                  | Con              | 2.30        | 3.25          | 2.33       | 3.50        | 2.85             | SHE,SC,SR,CT,RE,SD,MI |
| Sleep-Diary (Anel Pasic)                   | No                   | None                       | Free (NA)                   | Info              | 2.30        | 3.75          | 2.67       | 2.00        | 2.68             | SD                   |
| Sleep Smart (MindApps)                     | No                   | 5 (1)                      | 2.29€ (NA)                  | Con              | 2.60        | 2.12          | 2.17       | 2.17        | 2.26             | SHE,SR,RE,SD        |

Note: Con, contact details; CT, cognitive therapy; Em, emergency functions; IC, informed consent; Info, information on dealing with data; MHA, mobile health application; MI, mindfulness; Mo, safety measurements for mobile loss; Pri, privacy statement; Pw, password protection; Re, relaxation strategies; SC, stimulus control; SD, sleep diary; SHE, sleep hygiene education/psychoeducation; SR, sleep restriction.

*aPound was converted into Euro according to the exchange rate (1 GBP = 1.15€) on 03.03.2021, and dollar was converted into Euro according to the exchange rate (1$ = 0.84€) on 10.03.2021.

*bThe MHA “somnio” was classified as free of charge, as German users do not need to pay a fee if general care physicians or psychotherapists prescribe the MHA. However, the statutory health insurances have to pay 464,00€ per prescription.
| MHA name (developer)                                                                 | Available on iOS | User star rating (n ratings) | Annual cost basic (extended) | Security features | Engagement | Functionality | Aesthetics | Information | Overall quality | Treatment components |
|------------------------------------------------------------------------------------|-----------------|------------------------------|------------------------------|-------------------|-------------|---------------|------------|-------------|------------------|----------------------|
| Somnio (mentoro DE GmbH)                                                            | Yes             | 3.8 (47)                    | Free (NA)                    | Pw,Log,Pri,IC,Info,Con,Mo | 5.00        | 4.62          | 5.00       | 4.36        | 4.75             | SHE,SC,SR,CT,RE,SD,Mi |
| Soutien psy avec Mon Sherpa (Qare – consultations médicales)                        | Yes             | None                        | Free (NA)                    | Pw,Log,Pri,Info,Con     | 4.90        | 4.38          | 4.83       | 4.25        | 4.59             | SHE,CT,RE             |
| Sleep Cure (Sleep Cure)                                                             | No              | 1.7 (12)                    | Free (52.68€)                | Pw,Log,Pri,Info,Con     | 4.50        | 4.25          | 5.00       | 4.25        | 4.50             | SHE,SC,SR,CT,RE,SD,Mi |
| Insomnia Coach (US Department of Veterans Affairs)                                 | Yes             | 3.6 (13)                    | Free (NA)                    | Pri,IC,Info,Con,Em      | 4.30        | 4.12          | 4.50       | 4.79        | 4.43             | SHE,SC,SR,CT,RE,SD,Mi |
| HALEO – Sleep better within 2 weeks (HALEO Preventive Health Solutions Inc.)       | No              | 4.5 (38)                    | Free (1920.00€)              | Pw,Log,Pri,IC,Info,Con  | 4.10        | 4.25          | 4.83       | 4.25        | 4.36             | SHE,SC,SR,CT,RE,SD,Mi |
| BedTime Helper (PsyNovigo Ltd)                                                       | No              | 3.1 (23)                    | Free (NA)                    | Pri,IC,Info,Con         | 3.70        | 4.62          | 4.83       | 4.10        | 4.31             | SHE,SC,RE             |
| Sleeprate. Balance Your Sleep (Sleeprate)                                           | Yes             | 3.9 (29)                    | Free (9.99€)                 | Pw,Log,Pri,IC,Info,Con  | 4.00        | 4.12          | 4.67       | 3.71        | 4.13             | SHE,SC,CT,RE,SD,Mi    |
| Sleep School for Insomnia (Sleep School)                                            | Yes             | None                        | Free (NA)                    | Pw,Log,Pri,IC,Info,Con  | 4.20        | 4.25          | 4.00       | 3.92        | 4.09             | SHE,CT,MI             |
| Sleep Theory – Sleep Aid & Smart Alarm Clock (Nox Limited)                          | No              | None                        | Free (35.99€)                | Pw,Pri,Info,Con         | 4.10        | 3.62          | 4.17       | 4.00        | 3.97             | SHE,SC,SR,RE,SD      |
| InsomniaFix (NOVOS Behavioral Health Solutions, LLC)                                | No              | 4.1 (10)                    | Free (NA)                    | Pri,Info,Con            | 3.30        | 4.50          | 3.67       | 4.10        | 3.89             | SHE,SR,SD             |
| Circady Sleep Diary (Circady)                                                       | No              | 2.4 (14)                    | Free (NA)                    | Pw,Log,Pri,IC,Info,Con  | 3.40        | 4.38          | 3.83       | 3.75        | 3.84             | SD                   |
| CBT-i Coach (US Department of Veterans Affairs)                                     | Yes             | 3.8 (150)                   | Free (NA)                    | Pri,IC,Info,Con,Em      | 3.70        | 4.00          | 2.83       | 4.57        | 3.78             | SHE,SC,SR,CT,RE,SD,Mi |
| Night Owl – Sleep Coach (Mindware Consulting, Inc)                                  | Yes             | 3.5 (34)                    | 10.99€ (NA)                  | Pw,Log,Pri,Info,Con     | 3.00        | 4.12          | 3.17       | 3.64        | 3.48             | SHE,SC,CT,RE,SD,Mi    |
| Sleep Restore (Mark Grant)                                                          | No              | None                        | Free (9.99€)                 | Pri,IC,Info,Con         | 2.70        | 3.88          | 3.33       | 3.50        | 3.35             | SHE,RE               |
| Sleep Log Pro: The CBT-I sleep diary for insomnia (Mind and Body)                   | Yes             | None                        | 5.99€ (NA)                   | Pri,Info,Con            | 3.00        | 4.00          | 3.33       | 3.00        | 3.33             | SHE,SC,SR,SD          |
| Sleep Disorders (Subject Mastery Academy)                                           | No              | None                        | Free (NA)                    | Pri,Con                 | 2.30        | 4.38          | 3.17       | 3.40        | 3.31             | SHE                  |
| Sleep Log Free: The CBT-I sleep diary for insomnia (Mind and Body)                  | No              | None                        | Free (NA)                    | Pri,Info,Con            | 3.10        | 3.88          | 3.17       | 3.08        | 3.31             | SHE,SC,SR,CT,SD      |
| Phantasiereisen zum Einschlafen (start2dream.de)                                     | No              | 4.4 (778)                   | Free (5.49€)                 | Pri,Info,Con            | 2.50        | 4.38          | 2.67       | 3.20        | 3.19             | SHE,CT               |
| eezCBT – (CBT – Cognitive Behavioural Therapy) (Smash Appz)                          | No              | 4.4 (17)                    | Free (NA)                    | Pw,Pri,Info             | 3.00        | 3.25          | 3.00       | 3.17        | 3.10             | SHE,CT               |
| MHA name (developer)                                                      | Available on iOS | User star rating (n ratings) | Annual cost basic (extended)* | Security features | Engagement | Functionality | Aesthetics | Information | Overall quality | Treatment components |
|------------------------------------------------------------------------|-----------------|----------------------------|-------------------------------|-------------------|------------|--------------|------------|-------------|-----------------|----------------------|
| How to Cure Insomnia (Amamiya Apps)                                    | No              | None                       | Free (NA)                     | Pri,Info,Con      | 2.00       | 4.50         | 3.17       | 2.70        | 3.09            | SHE, CT               |
| How to Cure Insomnia (NC Media Solutions)                              | No              | None                       | Free (NA)                     | Con               | 2.10       | 4.75         | 2.17       | 3.12        | 3.04            | SHE, RE              |
| How To Treat Insomnia (freeCreativity2019)                             | No              | None                       | Free (NA)                     | Pri,IC,Info,Con   | 2.00       | 4.50         | 2.33       | 3.25        | 3.02            | SHE                  |
| insomnia (referencehunt)                                               | No              | None                       | Free (NA)                     | Con               | 1.70       | 4.12         | 2.50       | 3.60        | 2.98            | SHE                  |
| Sleep Smarter – Fight insomnia & improve sleeping (Boost Media)         | No              | None                       | Free (NA)                     | Pri,Info,Con      | 2.00       | 4.00         | 2.67       | 3.20        | 2.97            | SHE, SC              |
| Insomnia (FREE) (Yanz Apps)                                            | No              | 3.4 (5)                    | Free (NA)                     | Con               | 2.00       | 4.50         | 2.17       | 3.00        | 2.92            | SHE                  |
| Sleep Diary (Melon)                                                    | No              | None                       | Free (NA)                     | Info,Con          | 2.20       | 4.38         | 2.33       | 2.75        | 2.91            | SD                   |
| Bien dormir Mieux vivre (rifio)                                        | No              | None                       | Free (NA)                     | Con               | 2.10       | 3.88         | 2.33       | 3.25        | 2.89            | SHE, SC, RE          |
| Cognitive Behavioural Therapy (AppMaster365)                            | No              | 4.3 (9)                    | Free (NA)                     | Con               | 2.10       | 4.12         | 2.33       | 3.00        | 2.89            | SHE                  |
| Sleep Disorders And Problems (Twayesh Projects)                        | No              | None                       | Free (NA)                     | Pri,Info,Con      | 1.90       | 4.25         | 2.17       | 2.75        | 2.77            | SHE                  |
| Psychiatry Pro-Diagnosis, Info, Treatment, CBT & DBT (BDR limited)      | No              | None                       | Free (NA)                     | Pri,Info,Con,Em   | 2.40       | 3.25         | 2.00       | 3.33        | 2.75            | SHE, SC, SR, CT      |
| Sleep Aid App Free – Insomnia Cure App (Beatia)                        | No              | None                       | Free (NA)                     | Pri,Con           | 2.00       | 3.25         | 2.00       | 3.42        | 2.67            | SC                   |
| Insomnia (Yanz Apps)                                                   | No              | None                       | Free (NA)                     | Con               | 1.70       | 4.50         | 1.83       | 2.40        | 2.61            | SHE, SC              |
| Sleep Better Guide (Expert Health Studio)                              | No              | None                       | Free (NA)                     | Pri,IC,Info,Con   | 1.80       | 3.12         | 2.17       | 3.30        | 2.60            | SHE, SC              |
| Sleep Hygiene Guide (Creative Writing Apps)                            | No              | None                       | Free (NA)                     | Con               | 1.80       | 4.00         | 1.83       | 2.60        | 2.56            | SHE                  |
| Sleep Yoga & Meditation – Cure Insomnia & Snoring (Dr Zio – Yoga Teacher) | No              | None                       | Free (10.99€)                  | Pri,Info,Con      | 2.50       | 2.75         | 2.33       | 2.67        | 2.56            | SHE                  |
| Insomnia Treatment Remedies (StatesApps)                                | No              | 4.3 (6)                    | Free (NA)                     | Con               | 1.50       | 3.88         | 2.67       | 1.83        | 2.47            | SHE                  |
| Wie zu überwinden Schlaflosigkeit (Naura shaki)                         | No              | None                       | Free (NA)                     | Pri,Con           | 1.50       | 3.50         | 1.83       | 2.50        | 2.33            | SHE                  |

Note: Con, contact details; CT, cognitive therapy; Em, emergency functions; IC, informed consent; Info, information on dealing with data; MHA, mobile health application; MI, mindfulness; Mo, safety measurements for mobile loss; Pri, privacy statement; Pw, password protection; Re, relaxation strategies; SC, stimulus control; SD, sleep diary; SHE, sleep hygiene education/psychoeducation; SR, sleep restriction.

*Pound was converted into Euro according to the exchange rate (1 GBP = 1.15 €) on 03.03.2021, and dollar was converted into Euro according to the exchange rate (1 $ = 0.84 €) on 10.03.2021.

The MHA “somnio” was classified as free of charge, as German users do not need to pay a fee if general care physicians or psychotherapists prescribe the MHA. However, the statutory health insurances have to pay 464.00€ per prescription.
TABLE 5  Quality ratings per subscale using the MARS-G

|                  | Mean  | Standard deviation | Minimum | Maximum | n MHAs categorized as low (%) | n MHAs categorized as moderate (%) | n MHAs categorized as high (%) |
|------------------|-------|--------------------|---------|---------|-------------------------------|------------------------------------|---------------------------------|
| Overall quality  | 3.46  | 0.71               | 2.26    | 4.75    | 3 (5.7%)                      | 36 (67.9%)                        | 14 (26.5%)                      |
| Engagement       | 3.02  | 1.03               | 1.5     | 5       | 21 (39.6%)                    | 19 (35.8%)                        | 13 (24.5%)                      |
| Functionality    | 4.01  | 0.52               | 2.12    | 4.75    | 1 (1.9%)                      | 17 (32.1%)                        | 35 (66.0%)                      |
| Aesthetics       | 3.31  | 1.04               | 1.83    | 5       | 16 (30.2%)                    | 20 (37.7%)                        | 17 (32.1%)                      |
| Information      | 3.49  | 0.72               | 1.83    | 4.79    | 4 (7.5%)                      | 33 (62.3%)                        | 16 (30.2%)                      |
| Potential        | 2.58  | 0.85               | 1.25    | 4.88    | 31 (58.5%)                    | 18 (34.0%)                        | 4 (7.5%)                        |
| therapeutic gain |       |                    |         |         |                               |                                    |                                 |

Note: The categorization was based on following criteria: low rating: < 2.5; middle rating: ≥ 2.5 and < 4; high rating: ≥ 4.

MHA, mobile health application.

Inaccurate, lacking or misleading information may impact users’ safety (Albrecht, 2016; Huckvale et al., 2020). Our ratings indicated that most rated MHAs had a moderate information quality (62%). While 16 MHAs (30%) were of high information quality, there were also four MHAs (8%) that were of low information quality. Given the abundance of available MHAs targeting insomnia and the high variance in quality, the selection of a suitable MHA might be a particularly difficult task for healthcare seekers. Moreover, app store descriptions and user star ratings may be misleading in the selection process (Nicholas et al., 2015). However, several independent information platforms (e.g. mhad.science, mindapps.org) aim to provide reliable and publicly accessible information on the quality, scope, functionality and security features of MHAs. Yet, many healthcare seekers and providers are unaware of these initiatives. Hence, it appears to be important to disseminate information about these platforms (e.g. via primary care settings, social media) to increase their impact. Ultimately, the healthcare seekers themselves will decide on which MHA to use. Thus, it seems important to educate healthcare seekers on how to select a suitable MHA (e.g. evidence-based content, scientific evaluation).

While we were able to identify scientific evidence for 10 MHAs (19%), this evidence included only one randomized controlled pilot study, and results of this study yielded non-significant group differences between on-site CBT-I paired with a MHA and regular on-site CBT-I on insomnia severity (Koffel et al., 2018b). The other identified studies were observational (Eyal et al., 2020; Harbison et al., 2018), surveyed clinicians’ perception of the MHA (Kuhn et al., 2016), or investigated only the browser version (Lorenz et al., 2019). It appears that MHAs that have been scientifically evaluated are often not available in the app stores, whereas MHAs that are available in the app stores have often not been scientifically evaluated. Thus, evidence for the effectiveness of freely available MHAs is not sufficient. In fact, a recently published review by Aji et al. (2020) found that of eight scientifically evaluated MHAs targeting insomnia, only one MHA (i.e. “CBT-I coach”) was available in the app stores. Besides digitalized CBT-I programs that are exclusively available via MHAs, there is also an emerging number of scientifically evaluated digitalized CBT-I programs that are available via other modalities or which offer parts of the intervention via MHAs. Meta-analyses support the efficacy of these programs (Soh et al., 2020; Zachariae et al., 2016). However, the scientific evaluations of these programs focus on the browser-based versions of the programs, and it is not clear if the corresponding MHAs work the same way (Moshe et al., 2021). Consequently, scientific evaluations should study if the efficacy of browser-based CBT-I programs can be generalized to MHAs that deliver the same content. Moreover, the scientific community and healthcare systems should implement ways that facilitate the dissemination of MHAs that have been scientifically evaluated and proven to be effective. For example, Germany has established a billing model where scientifically evaluated MHAs can be prescribed by healthcare providers. It should be observed whether such approaches promote rigorous scientific evaluations of MHAs and their subsequent dissemination.

It seems important to include information on rationale, possible adverse effects and contraindications of sleep restriction, as sleep restriction is associated with adverse effects (e.g. excessive sleepiness, difficulty to concentrate; Kyle et al., 2011) and is contraindicated for certain conditions (e.g. sleep-disordered breathing or epilepsy; Spielman et al., 2011). Yet, while 16 MHAs featured sleep restriction, only four MHAs included such information. In addition to the aforementioned risks, the investigation showed that inadequate data protection measures may also pose risks for users. Despite these named issues, it seems promising that almost a third of the rated MHAs featured a combination of psychoeducational content/sleep hygiene, behavioural therapy, and cognitive therapy. In particular, the highest-rated MHAs, which are described in detail in Table S2, seem to have the potential to improve the care of insomnia, as they included high-quality content, precautions for user’s safety, and features to enhance user engagement. Nevertheless, to improve the care of insomnia and address the existing treatment gap, strategies to disseminate MHAs that have been scientifically proven to be effective need to be implemented.

4.1 | Strengths and limitations

We followed a well-established systematic approach for the evaluation of MHAs, including an extensive and systematic search, a
### TABLE 6  Synthesis evidence base

| MHA            | Reference                | CBT-i coach/Insomnia Coach* | Insomnia Coach/Insomnia Coach | Sleeprate/Eval (2020)* | NightOwl/Harbinson (2018)* |
|----------------|--------------------------|----------------------------|------------------------------|------------------------|-----------------------------|
| Study design   | Randomized controlled pilot study comparing onsite CBT-I with onsite CBT-I plus MHA | Survey of CBT-I clinicians (working for the US Department of Veterans Affairs clinics) | Randomized controlled study (for browser version of the MHA; did not evaluate the MHA itself) | Observational study (pre-post without control group) | Observational study (pre-post without control group) using participant sleep log data of the MHA |
| Sample size   | 18                       | 176                        | 52                          | 192                    | 157                        |
| Insomnia diagnosis according to | Not specified (referrals for CBT-I) | Not applicable | DSM-V & ISI ≥ 8 | No information | WASO > 29 min and SOL > 29 min |
| Summary results | Intention-to-treat analysis indicated no significant group differences for insomnia severity. Semi-structured interviews indicated an improvement in the accessibility of therapeutic materials and all participants reported that they would recommend the MHA to family and friends. | Surveyed clinicians indicated positive perceptions of the MHA and that the MHA may enhance the delivery of CBT-I in blended care models. | Significant differences (both within-group and between-group) on insomnia severity and significant within-group differences on all measured sleep diary parameters. | Significant within-group differences in SOL, WASO and SE. | Significant within-group differences in SOL, WASO, TST, and SE. |
| Results | -ISI (main effect for treatment condition):  d = 0.21 | Relative advantage \( M = 5.15 \) (SD = 0.79) | Complexit \( M = 5.74 \) (SD = 1.22) | Future use intention \( M = 6.22 \) (SD = 0.82) | Between group effect sizes: \(-ISI: d = 1.79\) Within-group effect sizes: \(-ISI: d = 1.59\) \(-SE: d = 1.16\) \(-SOL: d = 0.5\) \(-WASO: d = 1.02\) \(-TST: d = 0.45\) Restfulness: \(d = 1.48\) \(-Daytime\) performance: \(d = 0.99\) | -SOL (for participants who had initial SOL > 30 min): \(M = 53.9\) (SD = 20.8) \(t(69) = 2.9, p < 0.001\) \(p < 0.001\) \(p > 0.001\) | -SOL: \(M = 55.1\) (SD = 61.4) \(t(69) = 2.9, p < 0.001\) \(p < 0.001\) \(p < 0.001\) | -WASO: \(M = 68\) (SD = 80.9) \(t(69) = -5.9, p < 0.001\) \(p < 0.001\) \(p < 0.001\) | -SE: \(M = 75.9\) (SD = 85.8) to \(M = 85.8\), \(t(69) = 1.5\) \(p < 0.07\) \(p > 0.001\) \(p < 0.001\) | -TST from \(M = 6.5\) (SD = 2.3) to \(M = 6.9\) (SD = 2.0), \(t(69) = 2.9\) \(p < 0.002\) \(p > 0.001\) \(p < 0.001\) | -NWK from \(M = 2.6\) (SD = 3.1) to \(M = 2.2\), \(t(69) = -1.5\) \(p < 0.07\) \(p > 0.001\) \(p < 0.001\) |

Note: CBT-I, Cognitive Behavioural Therapy for Insomnia; D, Cohens D; DSM-V, Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition; ISI, Insomnia Severity Index; M, mean; MHA, mobile health application; NWK, number of awakenings; SD, standard deviation; SE, sleep efficiency; SOL, sleep-onset latency; TST, total sleep time; WASO, wake after sleep onset.

*aThe evidence from CBT-i Coach was counted as evidence for both “Insomnia Coach” and “CBT-i Coach”, as the MHA “Insomnia Coach” is an updated version of the MHA “CBT-i Coach”.

*Sample size of the here-presented results.

*Analysed subsample that experienced symptoms of insomnia.

*Analysed subsample that completed at least 50% of the program.

1According to the Centre for Evidence-Based Medicine, Oxford (OCEBM Levels of Evidence Working Group, “The Oxford 2011 Levels of Evidence”, Oxford Centre for Evidence-Based Medicine: http://www.cebm.net/index.aspx?o=5653).
screening based on pre-defined criteria, and a quality evaluation using an objective, reliable and valid scale (Messner et al., 2020; Stoyanov et al., 2015; Terhorst et al., 2020). Moreover, we evaluated MHAs available in German, English and French, which are the most commonly spoken languages in the European Union (European Commission, 2012).

Nonetheless, we are mindful of the limitations of this study. Given the volatility of the app market (Larsen et al., 2016), the present review must be understood as a snapshot at the time of the search conducted in September 2020. Additionally, the quality evaluation was conducted on a meta-level and not per treatment component. Thus, future studies should also evaluate the quality of the individual treatment components per MHA. Moreover, a limited MHA testing time of at least 15 min does not allow for an in-depth analysis of each app. Hence, while the MARS scale has shown its psychometric quality, it cannot be excluded that in-depth analysis on each MHA would provide differentiating insights. Given that the psychometric validation of the MARS did not include MHAs targeting insomnia (Terhorst et al., 2020), future studies should investigate the construct validity, concurrent validity and re-test reliability of the MARS in the domain of insomnia. Sleep restriction for example can be done in several ways and the details of the implementation matter. Therefore, ultimately scientific evidence on the effectiveness of each MHA is needed to conclude on its usefulness. Furthermore, the MARS ratings are based on the goals defined in the app stores. Correspondingly, MHAs with fewer goals (e.g. providing a sleep diary) may achieve higher ratings than more complex MHAs (e.g. providing a full CBT-I) if they have been evaluated to adequately achieve the defined goal, which may lead to an inflated rating of some of the MHAs. Hence, the ratings of MHAs with varying treatment components may not be comparable. Therefore, it is important to not solely rely on the MARS rating but to additionally consider the treatment components that are featured in the MHA when selecting an MHA. Moreover, we only included MHAs from the Apple App and Google Play Store that may have caused a selection bias. However, as the Apple App and Google Play Store compromise over 99% of the total market (StatCounter, 2021), the number of missed MHAs should be low. Additionally, only the German and British app stores were searched. Searches in app stores of other countries may have led to more MHAs meeting our eligibility criteria. According to our eligibility criteria, we only included MHAs featuring at least one CBT-I component. Thus, we did not include all MHAs targeting insomnia nor did we examine MHAs that feature circumscribed therapeutic supporting tools or other tools for healthcare providers and seekers. Moreover, privacy and data security features were only assessed descriptively in this study. Thus, for a full appraisal of the quality of MHAs presented in this study, an additional assessment of the technical quality would be necessary.

5 | CONCLUSION

A plethora of MHAs claiming to target insomnia exists in commercial app stores. Our rating of 53 MHAs available in the European app stores indicated a large variance in the quality using the MARS-G. Some of the rated MHAs achieved a high rating indicating the potential of MHAs in the care of insomnia. Yet, the rating also revealed shortcomings of some MHAs, and that the scientific evidence for MHAs available in the app stores is only preliminary. Given these findings, it seems important to provide healthcare seekers and providers with reliable information on the quality and content of the MHAs using independent information platforms. To realize the full potential of MHAs in the treatment of insomnia, the unique technical aspects of smartphones and persuasive design should be considered, and strategies to disseminate effective MHAs need to be developed.

AUTHOR CONTRIBUTIONS

Laura Simon and Lena Sophia Steubl initiated this study. Laura Simon, Lena Sophia Steubl, Josephin Reimann, Yannik Terhorst, Eva-Maria Messner and Harald Baumeister contributed to the study design and conceptualized the current research question. Michael Stach helped compile the mobile health application data. Laura Simon and Josephin Reimann rated the mobile health applications. Throughout the assessment, raters were supervised by Lena Sophia Steubl (psychotherapist in training), Eva-Maria Messner (licensed psychotherapist) and Lasse Bosse Sander (licensed psychotherapist). Laura Simon, Lena Sophia Steubl, Josephin Reimann and Yannik Terhorst conducted the data analyses. Laura Simon wrote the first draft of the manuscript. All authors revised and approved the final version of the manuscript for submission.

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CONFLICT OF INTEREST

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**SUPPORTING INFORMATION**

Additional supporting information may be found in the online version of the article at the publisher’s website.

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