

Report: Implementation actions for the WOREL guideline "Management of sleep disorders and insomnia in adults in primary care".

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Background:

Insomnia is an important health problem with a strong impact on the quality of life of individuals suffering from insomnia. Population surveys estimate that approximately 30% of adults suffer from insomnia (Van der Heyden et al., 2014). However, during the covid-19 crisis approximately 70% of adults reported insomnia (Demarest et al., 2021). In Belgium, this insomnia translates into a high level of consumption of sleep medication (13% of adults in 2018, 21% of adults during the corona crisis (Berete et al., 2020). Outside the covid period, there is a strong socio-economic gradient in both insomnia and sleep medication use, with higher prevalence and medication use among those with lower income or education levels (Gisle et al., 2020; Van der Heyden et al., 2014).

Insomnia has a strong impact on the well-being and quality of life of individuals (Hamilton et al., 2007; Ishak et al., 2012; Olfson et al., 2018), and has socio-economic consequences, including medical costs, but also impact on productivity (Daley et al., 2009; Hillman & Lack, 2013). In addition, insomnia is also a risk factor for several health problems (obesity, hypertension, depression, anxiety disorders, diabetes, cardiovascular disease, cognitive impairment), each with a strong personal and social cost and an impact on mortality (Ge et al., 2019; Hertenstein et al., 2019; Socias et al., 2021).

Summary of recommendations for treatment of sleep problems in primary care

Guidelines for treatment of insomnia prioritize a behavioral approach to sleep problems (Soong et al., 2021). The 2018 WOREL guideline (Cloetens et al., 2018) expands on this notion by recommending a stepped approach with the use of a sleep diary and sleep hygiene counselling as the first step (GPP), and CBTi-based behavioral interventions (stress reduction techniques, cognitive techniques, stimulus control, sleep restriction, and exercise) as the second step (GRADE 1B). If the GP's approach is inadequate or if the GP lacks expertise, or in the case of chronic insomnia with serious effects on functioning, the GP refers to a CBTi program (GRADE 1B). For the treatment of elderly people with insomnia, this approach is largely similar, but it is recommended that account be taken of the cognitive and physical capacities of the elderly person (GPP), and for elderly people in a residential care home it is recommended that, in consultation with the coordinating physician of the care facility (CRA-MCC), consideration be given to how the nurses and/or paramedical staff and/or external care providers can be deployed to apply the non-drug approach individually or at the level of the residential care home ('collaborative care') (GRADE 1C).

In the WOREL guideline, the use of sleep medication is limited to well-defined circumstances: it can be considered for acute and severe insomnia, and then only for a short period of time, not exceeding one week (GRADE 2C). Sleep medication is not recommended for patients with acute or chronic insomnia that are eligible for CBTi, or behavioral interventions based on CBT (GRADE 1B). There is no place for medication in the first-line approach to insomnia in the elderly (GRADE 1C).

When prescribing sleep medication, it is recommended that a stopping strategy be discussed (GRADE 1C) and that patients should always receive information about a non-drug treatment approach (GPP).

Methodology

Implementation of practice guidelines can be improved by taking a planned stepwise approach. In this approach, we conceptualize adherence to guideline recommendations as a behavior, that can be the target of a behavior change intervention (Fernandez et al., 2019; Peters et al., 2020). In the analysis of the implementation problem, we take a stepwise approach focusing first on problem identification (evidence practice gap, impact of non-adherence) and analysis of the context in which the behavior is taking place (analysis of barriers & facilitators, review of existing initiative). In a final step, we present an overview of key barriers for the target behavior and recommend interventions to be carried out as part of an implementation plan. These analyses are based on a review of international literature, supplemented by local (grey) literature and stakeholder consultation.

Step 1: Identification of evidence practice gap and selection of recommendations needing additional implementation support

Despite guidance, several data sources suggest a gap between current practice and recommended practices.

Data on sleep medication consumption and prescription.

National data from the Sciensano Health Survey 2018 about the medication use in the previous two weeks show an increase in use of sleep medication from 1997 (8.5%), reaching a peak in 2008 (14.3%) and then a slight decrease until 2018 (12.4%) (Gisle et al., 2020). Between 2008 and 2018, the use of sleep medication declined more sharply in Wallonia and Brussels, so that in 2018 there are no significant differences in the use of sleep medication between the different regions. Results of the national health survey, highlights a higher use of sleep medication among women and a strong increase with age: 25% in men over 75 years, 34% in women over 75 years. However, when looking across all age groups, a decrease in the use has been noticed in recent years, including in older individuals (Gisle et al., 2020; Péteïn et al., 2021). Research in nursing homes shows even higher rates of benzodiazepine use in this setting, with 52% of Belgian nursing home residents (median age 87 years) using sleep medication (Evrard et al., 2020).

Due to a lack of reimbursement for benzodiazepines in Belgian health insurance, there is no population level data on benzodiazepine prescriptions in the Farmanet database. However, despite a small decrease starting in 2016, pharmaceutical sales for sleep medication (2016 8.8 USD/capita, 2019 7.7 USD/capita; ATC N05C) remain of the one of the highest in Europe (OECD, 2022). Furthermore, in recent years, use of trazodone (often prescribed off-label for insomnia, contrary to guideline recommendations), has increased (FAGG, 2019)

Prescription data from the **intego database** (sample of Flemish general practitioners) show that 3% of the adult patient population received 3 or more prescriptions for benzodiazepines in 2000, and this was increased to 3.9% in 2015 (Katoonizadeh, 2020). Between 2000 and 2012, short-term use remained stable, but there was a sharp increase (39%) in the number of patients with 1 or 2 prescriptions after 2012. However, further analysis of this data shows strong differences in underlying trends based on gender and age group.

For chronic use of sleep medication, the highest use is observed in women over 65 years, increasing from 7% in 2000 to 11% in 2015, while groups with the lowest use (women and men of 18-44 years) maintained a similar prevalence of 1% over the years. However, between 2007 and 2015, there is a significant decline in use among men and women over 65 years (from 8% to 6% for men and from 12% to 11% for women).

Short-term use of sleep medication (1 or 2 prescriptions) remained globally stable between 2000 and 2012 (5%), although it is most common in women over 65 years (9%), women 45-64 years (7%), and men over 65 years (6%), and in each of these groups there is a decrease in use between 2000 and 2015. In contrast, it is to be noted that between 2012 and 2015, there is a significant increase of benzodiazepines use in men 18-44 years (from 1,5% in 2012 to 3,5% in 2015) and in women 18-44 years (from 3% in 2012 to 4% in 2015).

In a survey conducted by FAGG/FAMHP, 84% of participants had been taking sleep medication for 6 months or more (FAGG, 2021), although stakeholders suggested that this survey actively solicited participation from individuals with long-term sleep medication use.

Taken together, these data show that current consumption and prescription patterns are not in correspondence with recommendations from the WOREL guideline. The data are indicative of prolonged uses of sleep medication in the general population. The prolonged use of sleep medication in older individuals is especially problematic, given that the WOREL guideline explicitly recommends not to use sleep medication in older adults.

Data on use of behavioral interventions

There is currently no clear data available on the use of behavioral interventions by general practitioners or psychologists for the treatment of insomnia. A 2015 study with mystery shoppers by Test-Aankoop/Test Achats did show that only 11% of GPs gave adequate advice at first contact, and 94% prescribed medication. Among doctors who prescribed benzodiazepines, only a minority gave information on the maximum duration of use (Test Aankoop, 2015).

However, a survey among 84 GPs revealed that 74% of respondents claimed that they have educated about benzodiazepines when they prescribe those and 76% of them claimed to offer alternative management for insomnia (Ait-Mansour, 2020).

Evaluation of a select group of GPs trained to apply these alternative techniques (Creupelandt et al., 2019) shows that 6 months after training, only a minority of these GPs never use these interventions, although education on sleep hygiene (3% do not use) and ICE (*Ideas, Concerns and Expectations*) communication (15% do not use), education on stress vulnerability (19% do not use) are used by a larger group of GPs than sleep diaries (36% do not use), stimulus control techniques (32% do not use), or cognitive interventions (47% do not use). These data show that even in a highly motivated group of GPs, the implementation of behavioral techniques remains sub-optimal.

Impact of non-adherence to guideline recommendations

Uncertainty about long-term beneficial effects of sleep medication

Evidence on the efficacy of long-term use of benzodiazepines is absent, and only very limited for Z-drugs. Furthermore, psychopharmacological properties of these drugs (tolerance) are suggestive of poor long-term efficacy (Cloetens et al., 2018). Long term efficacy of behavioral treatments for insomnia in primary care are heterogeneous (Cheung, Jarrin, et al., 2019), but evidence is suggestive of long-term effectiveness both on sleep quality and quality of life, as positive effects on depressive symptoms and other mental health outcomes (Cheng et al., 2019; Espie et al., 2019; Scott et al., 2021), and direct comparisons suggest better long-term outcomes in treatment strategies that start with behavioral treatments compared to pharmacological treatment (Morin et al., 2020; Rios et al., 2019).

Side effects of benzodiazepines

The use of sleep medication is not without risks. Main side effects are daytime drowsiness, traffic accidents, risk of falling, memory and attention disruptions and dependence. Side effects are more

likely in older individuals, and risks associated with these side effects are also greater in older individuals. In addition, tolerance and withdrawal symptoms occur, and sleep medication has a dependency risk, so that use often becomes chronic (BCFI-CBIP, 2018). Behavioral treatments not only have better long-term efficacy (Mitchell et al., 2012; Rios et al., 2019) but also a better safety profile, although the reporting of adverse effects in older studies was often substandard, and recent studies also show side effects (fatigue, attention and memory complaints) during treatment (Condon et al., 2021). Finally, there are indications that continued sleep medication use reduces the efficacy of CBTi treatment, as combined treatment with CBTi and sleep medication shows no benefit over treatment with CBTi alone (Morin et al., 2009), these results can be explained by patients misattributing their treatment gains in combination treatment to sleep medication use, leading to a reduction in therapeutic gains when medication is stopped (Cheung, Ji, et al., 2019).

The combination of uncertainty about long-term beneficial effects and high risk of side effects has led several authors and agencies to designate prolonged use of benzodiazepines in elderly individuals as a low-value care practice that should be actively avoided and targeted for de-implementation (Brett et al., 2018; Klein & Mayer, 2017; Verkerk et al., 2018).

Continued treatment of chronic insomnia with sleep medication is also problematic from the perspective of equitable treatment. The prevalence of insomnia and sleeplessness is higher in individuals with lower socio-economic status and lower income levels (Van der Heyden et al., 2014). With pharmacological treatment being widespread, this provision of low value care further increases health inequalities, which may be even further exacerbated when access to behavioral treatments is inequitable. Similar treatment inequalities manifest in the treatment of insomnia in older individuals, which as a group are at greater risk of side effects compared to the general adult population but are more likely to receive pharmacological treatment. Furthermore, GP's are also more reluctant to deprescribe sleep medication in older adults, despite being aware of the heightened risk, further exacerbating health inequalities (Sirdifield et al., 2013). These findings were also corroborated by stakeholders during the stakeholder meetings.

Conclusion Step 1: targets for implementation

After stakeholder consultations, the following sets of recommendations were deemed a priority for additional implementation efforts:

1. Recommendations aimed to improve the provision of behavioral treatments. These include taking a stepwise approach to behavioral interventions, starting with sleep hygiene information and use of a sleep diary, followed by low intensity behavioral interventions, and finally referral to a CBTi-therapist.
2. Recommendations aimed to improve the quality of pharmaceutical treatment and reduce the risk of prolonged pharmaceutical treatment. These include the recommendation not to prescribe sleep medication in older individuals, to only prescribe sleep medication in patients presenting with acute and severe sleep problems and combine prescription of sleep medication with the provision of information and shared decision making, as well as planning follow up/monitoring, and discontinuation at the moment of first prescription.
3. Although specific recommendations on discontinuation/deprescribing in patients with current sleep medication use are not part of the WOREL-guideline, we feel that actions are also needed to support GP's and pharmacists with discontinuation/deprescribing in patients with existing prolonged sleep medication use.

Step 2: Context analysis

Analysis of barriers and facilitators was based on 2 systematic reviews of qualitative studies (Sirdifield et al., 2013, 2017), and a narrative review on barriers to CBTi treatment (E. Koffel et al., 2018). These reviews were supplemented by results from a Belgian survey on GP experiences (Anthierens et al., 2010) as well as a scoping review of Belgian grey literature (Janssens et al. in preparation) and a survey among stakeholders. Results of the context analysis were submitted for stakeholder review and further contextualized. In order to facilitate comparison of barriers listed by different sources, we used the theoretical domains framework to organize barriers and facilitators (Cane et al., 2012; Richardson et al., 2019).

Barriers from the GP's perspective

In a systematic review on GP beliefs, Sirdifield and colleagues (Sirdifield et al., 2013) show that management of sleeplessness and insomnia by GP's is not in accordance with practice guidelines, but is characterized by inconsistent strategies for prescribing management, using heuristic self-imposed rules, and resulting in behavioral differences between GPs, but also within individual practice.

The inconsistent management can be conceptualized as the results of mixed or incompatible attitudes related to benzodiazepine management. GPs indicate that benzodiazepines were overprescribed in the past, but do not see this past behavior as their sole responsibility, given high prescribing rates by psychiatrists (Sirdifield et al., 2013) or during hospital stays (De Keyser, 2017; Gijzen, 2017). GPs have a clear perception of changing norms of BZD prescriptions, but also may find these norms to be too restrictive (Sirdifield et al. 2013), and may find it difficult to question or change past prescriptions by colleagues; especially when these colleagues are more experienced (Metsers, 2020). Norms of benzodiazepine prescription are furthermore influenced by the GP's own use of benzodiazepines, which GP's have indicated to be high (Anthierens et al., 2007; Saeyns & Cammu, 2014). Furthermore, GP's are concerned about the problem of insomnia and its impact on the patient's quality of life (Anthierens et al., 2007). Prescribing sleep medication is therefore primarily a means of helping the patient, but it leads to tension between the willing to help the patient and the responsibility for minimizing benzodiazepine use (Sirdifield et al., 2013). There is a GP's perception of a '*deserving patient to receive benzodiazepine prescription*' based on a case-by-case (patient centered) management approach (especially if the patient is old, frail, with multiple conditions) and some GP's perception of 'patients expectations/motivations and ability to cope' that compete with recent recommendations (Sirdifield et al., 2013), especially behavioral treatments (Anthierens et al., 2010; E. Koffel et al., 2018). Although Many GP's share the belief that benzodiazepine are not a preferred treatment, they may subscribe to the belief that benzodiazepine might be 'the lesser evil -particularly for psycho-social problems', given the lack of availability of or access to nonpharmacological treatments. GP's can also be skeptical toward the efficacy of nonpharmacological approaches or feel that they lack the skill and expertise to make use of behavioral interventions (Sirdifield et al., 2013). Attitudes of the GPs may differ related to the task of new prescriptions, continuation, or discontinuation (Sirdifield et al., 2013). Finally, GP's experience the management of insomnia in primary care as a complex, demanding, and uncomfortable task (Sirdifield et al., 2013). Specific barriers to the use of behavioral interventions or referral to CBTi are a (perceived) lack of access, but also a lack of perceived efficacy of behavioral treatments and a beliefs that insomnia is a symptom of underlying condition rather than a specific syndrome needing treatment (E. Koffel et al., 2018).

Stakeholders added that GP's only have limited time available during consultation, and that they do not have the skills to adequately consult and manage sleep problems during this limited time, especially when insomnia is part of a complex psychosocial problem. However, other stakeholders

suggest that perceived time issues may be related to skills and beliefs about competency, as brief interventions within the consultation timeframe should be possible with additional training. Stakeholders also added that many GP's questioned the efficacy of behavioral methods, which may lead to a lack of motivation to provide behavioral treatments or seek training in behavioral interventions. Furthermore, some of the behavioral (e.g. sleep restriction) and cognitive interventions proposed by the guideline may take more intensive training to master than what is currently offered. Finally, stakeholders indicated social and environmental barriers in providing patients with referrals to CBTi or sleep clinics, citing stigma associated with psychosocial care as well as lack of access to these services, and a lack of availability and integration of behavioral practitioners (psychologists, nurses, case managers,...) in primary care.

Barriers at the level of psychologists

Currently, there is a lack of information on barriers related to the provision of evidence-based treatments for insomnia in Belgian psychologists. Surveys of psychologists in Canada, the United States, and Australia highlight a lack of knowledge, training, and experience with the treatment of insomnia. Psychologists reported a lack of formal training in treating sleep problems, but showed an interest in additional training (Meaklim et al., 2021; Zhou et al., 2021). Australian trainee psychologists reported low self-efficacy in treating insomnia, whereas practicing north American psychologists reported high levels of self-efficacy, but mainly endorsed sleep hygiene education as a first step treatment in their patient population.

Stakeholders suggested that many psychologists operating in primary care are currently not skilled in CBTi, or may hold competing treatment beliefs related to insomnia (seeing insomnia as a symptom of an underlying problem instead as a target for intervention). Stakeholders suggested that psychologists skilled in CBTi could also be more involved in the training or supervision of other health care practitioners but are currently not incentivized to do so.

Barriers from the patient's perspective

International studies suggest that poor sleep is often self-managed by patients, using sleep hygiene techniques, over the counter medicines or alcohol (Bartlett et al., 2008; Cheung et al., 2021; Henry et al., 2013), and patients using the pharmacy as a first point of care to seek help for their sleep problems (Cheung et al., 2014). Patient beliefs and attitudes influence help seeking and treatment that is received by patients. Help seeking is triggered by negative beliefs about insomnia and a perceived severe negative impact of insomnia on quality of life (Sirdifield et al., 2017). Additionally, help seeking is triggered by failed self-care attempts or perceived ineffectiveness of self-care strategies for insomnia (Sirdifield et al., 2017). Patients can therefore be disappointed with the initial treatment offered, especially if the GP suggests treatment that the patients already tried without success (Andries, 2019; De Walsche, 2020; Hens, 2020; Sirdifield et al., 2017).

Contrary to perceptions of GPs, many patients would not expect or prefer sleep medication as a first-line treatment for insomnia (Sirdifield et al., 2017). Furthermore, in patients who prefer not to take benzodiazepine, the lack of awareness of the availability of effective behavioral interventions may limit help seeking (E. Koffel et al., 2018).

Patients are aware that behavioral treatments take time and effort and identify these as important barriers. However, given the severity of their sleep problems, many patients are willing to invest the necessary time and effort, if this would help them sleep better (E. Koffel et al., 2018). Nevertheless even these patients struggle with systemic barriers to treatment including cost of treatment, lack of treatment availability, or waiting times (E. Koffel et al., 2018).

In general, patients are willing to take the time to receive information and discuss treatment options, weighing different aspects of treatment including difficulties with discontinuation of sleep medication (Andries, 2019; De Walsche, 2020; Hens, 2020; Sirdifield et al., 2017). However, patient preferences regarding information about adverse effects of benzodiazepines are ambiguous: for some this would drive their choice towards alternative treatments while for others it is an outcome, they are prepared to accept to improve their sleep (Sirdifield et al., 2017).

When addressing the issue of discontinuation of benzodiazepine use, the majority of patients viewed their medication as effective and are afraid that tapering use would have negative effects. They seem to be prompted to withdraw when they realize a psychological – rather than physical – dependence, when the drug is interfering with their life and their relatives (Sirdifield et al., 2017). Furthermore, patients viewed the prescription of sleep medication as an endorsement by their doctor about the need for pharmacological treatment and the safety of their medication (Sirdifield et al., 2017). In patients wanting to discontinue medication use, there was a concern of being unable to reduce medication use, a perception of not being supported by their GP, a fear of what would happen if they discontinued their medication, an absence of support network, all leading to continued sleep medication use (Sirdifield et al., 2017).

Stakeholders added that patient barriers to access CBTi can be a combination of geographical barriers and financial barriers, with lower cost group CBTi being only being available in sleep clinics, which are unevenly distributed geographically. High cost and limited access to CBTi also may drive inequity in receiving evidence-based care, in addition to a lack of socio-cultural adaptation of CBTi. Stakeholders also highlighted the role of GP in shaping patient beliefs about treatments, with the practice of referring to CBTi but also prescribing benzodiazepines to help cope with the waiting period giving mixed messages about optimal treatment for insomnia. With respect to discontinuation of sleep medication, stakeholders added that patient and GP prescription renewal behaviors may create a situation in which the request for prescription renewal is interpreted by the GP as a patient belief that sleep medication is necessary, whereas prescription renewal without further discussion is interpreted by the patient as an endorsement by the GP that sleep medication is safe and effective. This mismatch in beliefs highlights the need for explicit communication when prescription renewals are requested. Furthermore, stakeholders expressed the need for practical support with discontinuation, such as tapering schedules. Finally, stakeholders suggested that discontinuation is more difficult in elderly patients with very long-term medication use, and that specific barriers in this population need to be addressed.

Current initiatives and Previous Implementation efforts

Reviews on previous implementation efforts show actions have mainly focused on addressing patient barriers to discontinuation of sleep medication, GP-level barriers to EBP for insomnia, and health system barriers (Bourcier et al., 2018; Burry et al., 2022; King et al., 2021).

Interventions aimed at increasing awareness of risks associated with sleep medication, an increasing self-efficacy and skills related to sleep medication reduction have been carried out in a traditional GP led format (focusing on case finding, information provision and support by the GP), as well as in community pharmacy settings (focusing on direct to patient provision of information and tapering support tools, including signposting to GP or pharmacist) (Martin et al., 2018; Tannenbaum et al., 2014).

GP directed interventions have mainly focused on education and skills training, sometimes in combination with other effective implementation strategies based on the electronic patient record, such as audit & feedback or clinical decision support. These interventions have resulted in reduction

in benzodiazepine prescriptions (Bourcier et al., 2018; Burry et al., 2022). In Belgian primary care, the BelPEP initiative has provided GP's and pharmacists with tools and training on evidence-based practice for insomnia, including nonpharmacological management and advice for discontinuation.

In general, multifaceted, and active strategies have been found to be more effective in changing benzodiazepine prescriptions compared to compared to single, more passive interventions (Bourcier et al., 2018). However, many educational interventions have been poorly designed and evaluated (King et al., 2021). Furthermore, there has been a lack of extensive research on more intensive strategies to increase implementation evidence-based practice for insomnia, although findings from implementation interventions in targeting other problems suggest that these strategies (i.e. facilitation, use of local champions or change agents) are effective (Baskerville et al., 2012; Damschroder et al., 2021; Gulliford et al., 2019), and qualitative evaluation of ongoing CBTi implementation suggest the importance of these strategies (E. Koffel & Hagedorn, 2020).

Research on the provision of evidence based interventions by psychologists has highlighted that passive dissemination or one-off trainings increase knowledge but do not change psychologist behaviors, and that more intensive training trajectories are needed to increase the uptake of evidence-based interventions by psychologists (Frank et al., 2020). This finding highlights a discrepancy between the (potential) reach of trainings and their efficacy. Specific to CBTi, training within the Veterans Administration in the United States has shown the efficacy of a longer term (3-day) training with additional consultation/supervision (Karlin et al., 2013). Current training initiatives in Belgium (Dutch-language training on CBTi by the Belgian Association for Sleep Science and French-language inter-university training on CBTi take such an intensive approach but are limited in reach (training around 40 practitioners/year combined).

Recently, a free, online English-language training module has been developed that aims to deliver at least minimal proficiency in CBTi (Taylor et al., 2021). This training has been found acceptable by participating practitioners and has shown changes in CBTi core skills, but so far, impact on clinical practice has not been evaluated (Wilkerson et al., 2022).

Several system-level interventions have been used to reduce benzodiazepine prescriptions. These interventions include restrictions on maximal duration or renewal of benzodiazepines, or additional restrictions due to "upscheduling" of specific medications. Evaluations show that these interventions can be highly effective, leading to reductions of up to 85% of prescriptions for targeted medications (Bourcier et al., 2018; Burry et al., 2022). However, these interventions have also led to switching to other non-recommended sleep medication such as histamine H1 antagonists or barbiturates (Bourcier et al., 2018).

In Belgium, riziv-inami does not reimburse benzodiazepines and z-drugs. In the Netherlands, ending reimbursement has led to a 12% reduction in prescription of targeted medication, but effects were limited to a reduction in first-time prescriptions. Furthermore, a lack of access to nonpharmacological interventions may have limited the efficacy of this intervention (Hoebert et al., 2012). Finally, stronger restrictions on pharmaceutical marketing to doctors by local health systems have been shown effective in reducing prescriptions of sleep medication (Larkin et al., 2017).

With respect to increased use of CBTi, system level interventions have been carried out in integrated health care systems to increase access to CBTi, with a focus on competency based training for psychologists working in primary care mental health (Karlin & Cross, 2014). Furthermore, shorter/low-intensity versions of CBTi have been developed, as well as group-based and online/app based CBTi, which would address some of the barriers associated with current more intense CBTi treatments. While the efficacy of these alternatives has been positively evaluated (E. A. Koffel et al.,

2015; Kwon et al., 2021; Soh et al., 2020), their implementation has not been evaluated to the same extent as common CBTi (E. Koffel et al., 2018). For patients receiving CBTi, outcomes have been very successful, with remission rates matching those observed in RCTs (Trockel et al., 2014; Wu et al., 2015). However, more recent evaluations highlight current implementation problems in terms of access, with GPs being unaware of the availability of CBTi at their center and primary care psychologists needing to spend most of their work time on other mental health problems, leaving only limited time for the treatment of insomnia (Ulmer et al., 2017). Brief behavioral interventions have been successfully carried out by primary care nurses (Bothelius et al., 2013; Espie et al., 2007; Sandlund et al., 2018; Torrens et al., 2021; Van der Zweerde et al., 2020), and a clinical trial evaluating physiotherapist-led CBTi is currently under way in Belgium (Malfliet et al., 2019). Furthermore, pilot interventions in Australia and Canada have furthermore sought to expand consultation roles of pharmacists by including brief behavioral interventions, showing promising results (Fuller et al., 2016; Nurkowski et al., 2020).

Stakeholders indicated that foreign examples of (implementation) interventions go beyond what has currently been offered or piloted in the Belgian health care context. Stakeholders suggested using a multi-channel approach, in which patients receive information and support at different places (not only from GP's). They also suggested that increasing training and continued supervision on the use of behavioral treatments in non-psychologists may help with increasing access to behavioral techniques and could increase the use of behavioral techniques after initial training. Furthermore, stakeholders suggested to focus more on exercise or physical activity as a sleeping aid, or also include phytotherapy as a treatment option, although the level of evidence of these methods is currently more limited.

Step 3: Implementation plan

Matching barriers to actions

Based on the analysis of existing barriers, and building upon analysis by Sirdifield et al. (2013), we suggest that interventions to improve guideline-based practice for insomnia should focus on a selection of key barriers:

1. Interventions need to correct misconceptions about sleep and treatment of sleep problems in patients and health care providers. Specific attention should be paid to potential mismatches between practitioner beliefs and patient preferences as well as practitioner beliefs on the efficacy of behavioral interventions.
2. In health care practitioners, interventions are needed to increase the skill and self-efficacy of practitioners. This includes interventions on skills related to communication about patient beliefs about sleep and treatment options, skills to provide behavioral interventions and aid discontinuation of sleep medication and interventions to provide procedural knowledge on how to refer and treat patients with insomnia.
3. Interventions should consider patient care trajectories and the current context of healthcare, making use of current patient interactions in primary care concerning sleep, and consider previous self-care and help-seeking experiences of the patient
4. Finally, interventions are needed to reduce environmental barriers, such as time constraints, lack of access and cost of effective interventions.

Matching potential interventions to these barriers, our proposed intervention strategy (cf. Figure 1) is to implement a care pathway for sleep problems that leverages patient health care interactions with the pharmacist and the GP. Implementation of this care pathway is not the only implementation option but can be seen as an example on how implementation efforts will need to match barriers in order to be successful.

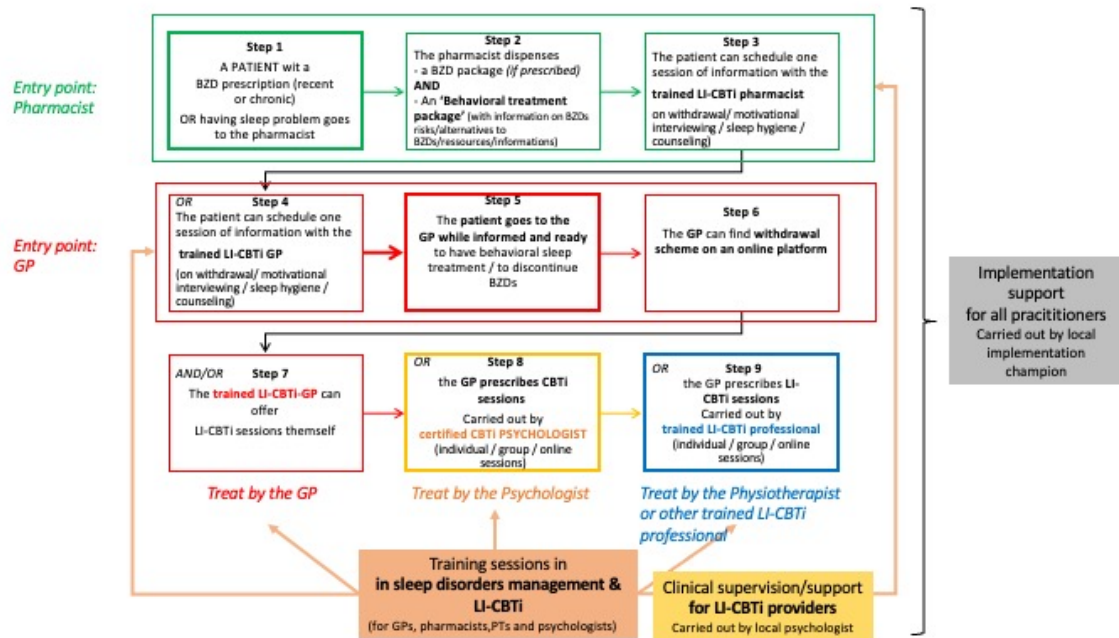


Figure 1: Outline of proposed care pathway for sleeping problems in primary care

During implementation of the care pathway, both the GP and the pharmacist will be trained to provide consultation and brief behavioral interventions, and will be equipped to prevent the use of sleep medication (in accordance with the Worel guidelines), as well as aid discontinuation of sleep medication use. Pharmacists and GP's will have the option to coordinate care with each other, as well as refer to other primary care practitioners, which will be trained to provide CBTi or brief behavioral interventions (Low-Intensity CBTi : LI-CBTi) (psychologists, physiotherapists, case managers, ...). The intervention strategy maximizes valorization of previous materials and initiatives that have been carried out with the aim of reducing benzodiazepine use, but aims to further integrate and support these initiatives, as well as target ongoing barriers that were previously not targeted. Training of pharmacists and general practitioners will make use of existing training materials (e.g. hulpmiddelenboek, e-learning and LOK, MFO training materials), but will be supported by a primary care psychologist providing feedback and support to practitioners at the local level. Training of CBTi psychologists will be based on existing training models (BASS, interuniversity collaboration), with additional attention to the role of primary care psychologists in supporting other health care professionals in providing LI-CBTi interventions. As in other proposed implementation projects, implementation of the different interventions will be supported local level by one of the health care providers taking up the role of local implementation champion, providing feedback and acting as a primary contact point for implementation support for their peers.

Funding for different tasks could be provided by ongoing actions (e.g. Funding of MFO by riziv-inami, LOK trainers funded by BelPEP, CBTi consultations delivered by primary care psychologists), with additional implementation tasks being funded by the implementation project. Ideally, local champions will have access to local indicators of implementation success, which will aid their

feedback efforts. Data collection throughout the project could also help make the case for reimbursement of tasks (e.g. reimbursement of behavioral interventions by different health care providers) when the implementation project has ended.

Detailed information on the different barriers the intervention is acting on is provided in Appendix 1.

Conclusion: Recommendations for implementation projects on sleep problems

Treatment of sleep problems in primary care is currently not in accordance with clinical practice guidelines. A lack of use of behavioral interventions or CBTi and an overuse of sleep medication to treat sleep problems results in limited treatment efficacy and increased adverse outcomes.

Previous efforts to change treatment of sleep problems in primary care have mainly focused on education of general practitioners and pharmacists, as well as small scale skills training, but research suggests ongoing barriers to evidence based treatment for sleep problems. Based on analysis of the key barriers and an evaluation of existing implementation interventions, we suggest continued efforts are needed to correct misconceptions about sleep and sleep treatment in patients and health care providers and provide health care providers with the skills to carry out consultations and brief behavioral interventions on sleep problems, with the support and supervision of CBTi psychologists or referral when needed. Furthermore, implementation of a care pathway on sleep problems can help to reach patients at the point when they start seeking help. Ideally, the implementation of a care pathway on sleep problems is supported by local champions and guided by continuous feedback on key quality indicators. Finally, the provision of remuneration for novel or additional tasks for health care practitioners would facilitate the success of the implementation.

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Appendix 1: Barriers addressed by the different steps of the implementation intervention

| Aim of the step in the implementation intervention | Barriers from the GP's perspective | Barriers/leverages from the patient's perspective | Barriers from the psychologist's perspective |
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| <p>Step 1 Contact with the patient who goes to the pharmacy for sleep disorders (with/without BZDs prescription)</p> | | <ul style="list-style-type: none"> - <i>Patient's belief that the pharmacy is the first point of care to seek help for their sleep problems</i> | |
| <p>Step 2 While having sleep disorders, the pharmacist dispenses the 'Behavioral treatment package', a tool for raising awareness of patient (about alternative methods for sleep disorders/BZDs risks/BZDs withdrawal)</p> | <ul style="list-style-type: none"> - <i>GP's only have limited time available during consultation</i> - <i>Stigma associated with psychosocial care</i> | <ul style="list-style-type: none"> - <i>Patient's negative beliefs about insomnia and a perceived severe negative impact of insomnia on quality of life</i> - <i>Previous failed self-care attempts or perceived ineffectiveness of self-care strategies for insomnia</i> - <i>Disappointment if the treatment offered by the GP was previously tried without success</i> - <i>Time and effort related to behavioral treatments</i> - <i>Preference regarding the information about adverse effects of BZDs are ambiguous and may drive to (1) accept the adverse effect of BZDs in order to improve their sleep, or to (2) drive the choice towards alternative treatments</i> - <i>Renewal of BZDs prescription without further discussion interpreted by the patient as an endorsement by the GP of sleep medication as a treatment strategy</i> - <i>Patients are afraid that tapering BZDs use would have negative effects on their sleep</i> - <i>Patients are concerned of being unable to reduce medication use</i> - <i>Patients seem to be prompted to withdraw BZDs when they realize a psychological – rather than physical – dependence, when it is interfering with their life and relatives (leverage)</i> | |

Appendix 1: Barriers addressed by the different steps of the implementation intervention

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| <p>Step 3 Information session to the patient (given by the trained LI-CBTi pharmacist)</p> | <ul style="list-style-type: none"> - <i>GP's only have limited time available during consultation</i> - <i>The GP's perception of 'patients expectations/motivations and ability to cope'</i> - <i>Stigma associated with psychosocial care</i> | <ul style="list-style-type: none"> - <i>Patients viewed the prescription of sleep medication as an endorsement by their doctor about 'the need' for pharmacological treatment and the safety of their medication</i> - <i>Patient's negative beliefs about insomnia and a perceived severe negative impact of insomnia on quality of life</i> - <i>Previous failed self-care attempts or perceived ineffectiveness of self-care strategies for insomnia</i> - <i>Disappointment if the treatment offered by the GP was previously tried without success</i> - <i>Time and effort related to behavioral treatments</i> - <i>Preference regarding the information about adverse effects of BZDs are ambiguous and may drive to (1) accept the adverse effect of BZDs in order to improve their sleep, or to (2) drive the choice towards alternative treatments</i> - <i>Renewal of BZDs prescription without further discussion interpreted by the patient as an endorsement by the GP of sleep medication as a treatment strategy</i> - <i>Patients are afraid that tapering BZDs use would have negative effects on their sleep</i> - <i>Patients are concerned of being unable to reduce medication use</i> - <i>Patients have a perception of not being supported by their GP and feel an absence of support network</i> - <i>Patients seem to be prompted to withdraw BZDs when they realize a psychological – rather than physical – dependence, when it is interfering with their life and relatives (leverage)</i> - <i>The role of GP in shaping patient beliefs about treatments, with the practice of referring to CBTi but also prescribing benzodiazepines to help cope with the waiting (leverage)</i> | |
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Appendix 1: Barriers addressed by the different steps of the implementation intervention

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| <p>Step 4 Information session to the patient (given by the trained LI-CBTi GP)</p> | <ul style="list-style-type: none"> - <i>GP's only have limited time available during consultation</i> - <i>GP's do not have the skills to adequately consult and manage sleep problems (during the limited time of consultation)</i> - <i>The GP's perception of 'patients expectations/motivations and ability to cope'</i> - <i>GPs feel that they lack the skill and expertise to make use of behavioral interventions</i> - <i>Stigma associated with psychosocial care</i> | <ul style="list-style-type: none"> - <i>Patients viewed the prescription of sleep medication as an endorsement by their doctor about 'the need' for pharmacological treatment and the safety of their medication</i> - <i>Patient's negative beliefs about insomnia and a perceived severe negative impact of insomnia on quality of life</i> - <i>Previous failed self-care attempts or perceived ineffectiveness of self-care strategies for insomnia</i> - <i>Disappointment if the treatment offered by the GP was previously tried without success</i> - <i>Time and effort related to behavioral treatments</i> - <i>Preference regarding the information about adverse effects of BZDs are ambiguous and may drive to (1) accept the adverse effect of BZDs in order to improve their sleep, or to (2) drive the choice towards alternative treatments</i> - <i>Renewal of BZDs prescription without further discussion interpreted by the patient as an endorsement by the GP of sleep medication as a treatment strategy</i> - <i>Patients are afraid that tapering BZDs use would have negative effects on their sleep</i> - <i>Patients are concerned of being unable to reduce medication use</i> - <i>Patients have a perception of not being supported by their GP and feel an absence of support network</i> - <i>Patients seem to be prompted to withdraw BZDs when they realize a psychological – rather than physical – dependence, when it is interfering with their life and relatives (leverage)</i> - <i>The role of GP in shaping patient beliefs about treatments, with the practice of referring to CBTi but also prescribing benzodiazepines to help cope with the waiting (leverage)</i> | |
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Appendix 1: Barriers addressed by the different steps of the implementation intervention

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| <p>Step 5 The patient is the one who makes the informed decision to engage in behavioral sleep treatment / discontinue BZD use</p> | <ul style="list-style-type: none"> - <i>The role and responsibility of the GP</i> - <i>BZDs prescription by a third party (difficult to question past prescriptions by peers)</i> - <i>Tension between the willing to help the patient and the responsibility for minimizing BZD use</i> - <i>The 'deserving patient to receive BZD prescription'</i> - <i>The GP's perception of 'patients expectations/motivations and ability to cope'</i> - <i>The GP's belief that BZD might be 'the lesser evil -particularly for psycho-social problems'</i> | | |
| <p>Step 6 Sleep disorder's management tools in an online platform (e.g. withdrawal scheme)</p> | <ul style="list-style-type: none"> - <i>The management of insomnia in primary care is as a complex, demanding and uncomfortable task for GPs</i> - <i>Need for practical support for BZDs discontinuation (for the GP and the patient), such as tapering schedules</i> | <ul style="list-style-type: none"> - <i>Patients have a perception of not being supported by their GP and feel an absence of support network</i> | |
| <p>Step 7 LI-CBTi sessions offered by trained GPs to the patient</p> | <ul style="list-style-type: none"> - <i>The lack of availability of or access to nonpharmacological treatments</i> | <ul style="list-style-type: none"> - <i>The help seeking is limited by a lack of awareness of the availability of effective behavioral interventions</i> - <i>High cost and limited access to behavioral treatment - CBTi</i> - <i>Lack of behavioral treatment availability (and waiting time)</i> | |
| <p>Step 8 CBTi sessions offered by psychologists to the patient</p> | | <ul style="list-style-type: none"> - <i>The help seeking is limited by a lack of awareness of the availability of effective behavioral interventions</i> - <i>Lack of behavioral treatment availability (and waiting time)</i> | |
| <p>Step 9 LI-CBTi sessions offered by other trained primary care professionals (PTs, case managers, practice nurses) to the patient</p> | <ul style="list-style-type: none"> - <i>The lack of availability of or access to nonpharmacological treatments</i> | <ul style="list-style-type: none"> - <i>The help seeking is limited by a lack of awareness of the availability of effective behavioral interventions</i> - <i>High cost and limited access to behavioral treatment - CBTi</i> - <i>Lack of behavioral treatment availability (and waiting time)</i> | |

Appendix 1: Barriers addressed by the different steps of the implementation intervention

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| <p>Training sessions in sleep disorders management & LI-CBTi for GPs, pharmacists, PTs CBTi training for primary care psychologists</p> | <ul style="list-style-type: none"> - <i>GP's beliefs that insomnia is a symptom of underlying condition rather than a specific syndrome needing treatment</i> - <i>GPs are skeptical toward the efficacy of nonpharmacological approaches (the lack of perceived efficacy to behavioral interventions or CBTi)</i> - <i>GP's lack of motivation to provide behavioral treatments</i> - <i>GPs feel that they lack the skill and expertise to make use of behavioral interventions</i> - <i>Some of the behavioral (e.g. sleep restriction) and cognitive interventions proposed by the guideline may take more intensive training than what is currently offered</i> - <i>Lack of availability and integration of behavioral practitioners (psychologists, nurses, case managers,...) in primary care</i> | <p>- <i>Lack of socio-cultural adaptation of CBTi</i></p> | <ul style="list-style-type: none"> - <i>lack of knowledge, training, and experience with the treatment of insomnia</i> - <i>Not enough psychologists skilled in CBTi</i> - <i>Competing treatment beliefs related to insomnia (seeing insomnia as a symptom of an underlying problem instead as a target for intervention)</i> - <i>Involvement of skilled psychologists in CBTi in the training of other HCPs</i> |
| <p>Supervision/support of LI-CBTi providers by CBTi Psychologists</p> | <ul style="list-style-type: none"> - <i>GPs feel that they lack the skill and expertise to make use of behavioral interventions</i> - <i>Lack of perceived effectiveness of behavioral treatments</i> - <i>discomfort associated with providing behavioral interventions</i> | | |
| <p>Health care providers act as Local Champions for implementation of the Care Pathway</p> | <ul style="list-style-type: none"> - <i>Limited knowledge on the availability and referral options for behavioral interventions</i> - <i>Negative attitudes on behavioral interventions, including Lack of perceived effectiveness.</i> - <i>Lack of availability and integration of behavioral practitioners (psychologists, nurses, case managers,...) in primary care</i> - <i>Social norms on benzodiazepine use and provision of behavioral interventions</i> | | |

Appendix 1: Barriers addressed by the different steps of the implementation intervention

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| Implementation plan as a whole | <ul style="list-style-type: none">- <i>The management of insomnia in primary care is as a complex, demanding and uncomfortable task for GPs (he's is not alone-in a loop of HCP)</i>- <i>BZDs prescription by a third party (difficult to question past prescriptions by peers)</i>- <i>Prescriptions norms « too restrictive »</i>- <i>Prescribing BZDs = helping the patient</i> | | |
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Appendix 1: Barriers addressed by the different steps of the implementation intervention