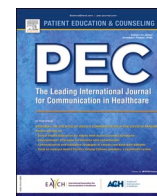




Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Elsevier hereby grants permission to make all its COVID-19-related research that is available on the COVID-19 resource centre - including this research content - immediately available in PubMed Central and other publicly funded repositories, such as the WHO COVID database with rights for unrestricted research re-use and analyses in any form or by any means with acknowledgement of the original source. These permissions are granted for free by Elsevier for as long as the COVID-19 resource centre remains active.



Co-design to increase implementation of insomnia guidelines in primary care

Kristien Coteur^{*}, Catharina Matheï, Birgitte Schoenmakers, Marc Van Nuland

Department of Public Health and Primary Care, KU Leuven, Belgium

ARTICLE INFO

Keywords:

Co-design
Patient involvement
Patient education
Insomnia
Primary health care research
General practice
Patient-centered design

ABSTRACT

Background: Sleep disorders, including insomnia, are widespread problems, which have increased during the COVID-19 pandemic. Guidelines for the treatment of insomnia prioritize non-pharmacological interventions. Nevertheless, primary care professionals lack well-developed material for patient education, that could help implement the treatment guidelines in Flanders, Belgium.

Objective: This project's purpose is to develop complementary, written educational material, grounded in the principles of evidence-based practice, for primary care.

Patient Involvement: This co-design project involved patients and health professionals. Special attention was given to including patients with low health literacy, and empowering patients when designing in mixed groups.

Methods: Based on the framework of Sanders and Stappers (2014), data were collected and analyzed in four phases. Pre-design, needs were explored using think-aloud studies and focus groups. Next, for generative purposes, the design studio method was used. Then, evaluation of the prototype happened with another series of think-aloud studies. Finally, post-design, implementation of the product was evaluated with a short survey.

Results: Twenty-five participants (10 patients and 15 healthcare professionals) contributed to the development of an educational patient leaflet called *Ssssst. How do you sleep (at night)?* Out of 30 professionals who received the printed leaflet for use in practice, 17 provided feedback after six months. Generally, the leaflet was well received. Visual design aspects stimulated use in practice.

Discussion: Written and visual materials aid primary care professionals to educate patients on sleep and insomnia. This supporting tool also stimulates self-management in patients. Although inspiring and educational for all stakeholders, a co-design approach is no guarantee for the product to “fit all”.

1. Introduction

Sleep disorders and insomnia are widespread problems, with prevalence of chronic insomnia varying from 6 % to 76 % worldwide pre-pandemic, depending on the diagnostic and screening methods used [1–5]. In 2021, the prevalence of sleep disorders in Belgium increased to 71 %, as measured with the SCL-90R, a validated questionnaire that was also used in 2013, when prevalence was at 30 % [6]. To treat sleep disorders, international guidelines stress the importance of non-pharmacological interventions [7,8]. However, the prevalence of hypnotic use remains high. In Belgium, in 2018, 12 % of people older than 15 used benzodiazepine receptor agonists (BZRA) [5].

Research shows that non-pharmacological interventions can provide a healthy alternative for medication, and support the discontinuation of current use of hypnotics [9–11]. These interventions are often focused

on patient education and tools for self-management. Ideally, interventions happen during a consultation in which the health professional has ample time to provide information tailored to the patient's needs and context [7–11].

Although a tailored transfer is usually valued over general written information, previous studies have shown that complementary written health information is beneficial in improving knowledge and patient satisfaction [12–21]. It allows patients to retain and reread the information whenever needed, and supports them to take responsibility of their own care [18,22]. However, patient education materials are often inaccessible for low health literacy populations, and not balanced with regard to information on benefits and harms [23]. As health literacy is another important aspect of engaging patients [24–27], visual aids are particularly useful when providing education to patients with limited health literacy [26,28].

^{*} Correspondence to: Kapucijnenvoer 7 – box 7001, 3000 Leuven, Belgium.

E-mail address: kristien.coteur@kuleuven.be (K. Coteur).

<https://doi.org/10.1016/j.pec.2022.08.018>

Received 3 February 2022; Received in revised form 5 July 2022; Accepted 27 August 2022

Available online 30 August 2022

0738-3991/© 2022 The Authors. Published by Elsevier B.V. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

In Belgium, insufficient validated material is available for primary care professionals to focus on the recommended non-pharmacological interventions. Although the federal government launched a patient leaflet in 2018, with advice on avoiding hypnotics and basic sleep hygiene tips [29], it did not inform about sleep patterns, sleep variability, cognitive techniques that have proven effect in the treatment of insomnia, nor did it acknowledge or provide tips to handle the impact of insomnia on daily life.

2. Objectives

In response to the lack of validated educational materials, this project aims to:

- 1. develop written educational material for a wide public with sleep problems in Flanders, Belgium
- 2. support non-pharmacological treatment of insomnia by rooting the content of the material in the principles of cognitive behavioral therapy for insomnia (CBTi), as recommended by evidence-based guidelines [7,8]
- 3. adhere to good practices [24–26,30,31] by involving both patients and health professionals from multiple disciplines in the development.

3. Methods

3.1. Study design

Based on the co-design framework of Sanders and Stappers (2014), health professionals, patients and researchers created a product in four phases. The method for each phase was selected by the expert steering committee from a list of participatory research methods, including user-centered design and usability testing, based on prior literature review (cfr. Appendix A).

In the pre-design phase, research focused on the larger context [32] by exploring needs of patients and health professionals. In the generative phase, they were brought together to create concepts for a prototype. A method that included sketching was selected, as previous research showed that imagery is beneficial when designing for patients with limited literacy [26,33]. Next, the prototype was evaluated by both groups. Finally, post-design, the use of the product was evaluated [32]. The project received ethical approval and occurred over seven months, between November 2019 and December 2021. Written informed consent was provided by all participants, separately for each phase.

3.2. Participants

Purposive sampling enabled obtaining a wide range of perspectives, experiences, health literacy, and information needs. Eligible for participation were non-institutionalized adults (18+), with current or past insomnia, able to read, write and speak Dutch, and all Flemish health professionals who encounter insomnia in their daily practice.

Recruitment occurred via the researchers' networks, including the university's network of patient representatives, and social media campaigns.

3.3. Data collection

3.3.1. Sample characteristics

All participants completed a demographic data survey, including age, sex, province of living, and profession. In the pre-design and generative phase, they also completed the Insomnia Severity Index (ISI) with temporal reference period of one month [34], and the short version of the European Health Literacy Survey Questionnaire (HLS-EU-Q16) [35]. The results enabled the researchers to verify the involvement of low-literate patients and insomniacs.

3.3.2. Pre-design phase

3.3.2.1. *Think-aloud studies.* At the beginning of the project, the aim was to confirm patients' need for new material and map pitfalls for future products by evaluating current material. Feedback from patients would also contribute to the focus groups with professionals. Think-aloud studies, originated in usability testing [36,37], were the preferred method.

While reviewing information leaflets and tools about insomnia, patients verbalized their experience, including thoughts and feelings. The Dutch patient materials under evaluation were freely available, through Google search, and snowballing of known sources. Both printed and online information (websites) were reviewed.

These were individual sessions, which were video-recorded. Using field notes for data collection, an observer noted all important remarks and possible difficulties. After review and completion of these notes by a second researcher, the videos were deleted.

3.3.2.2. *Mini focus groups.* Focus groups were organized to obtain a multidisciplinary perspective on professionals' needs concerning the treatment of insomnia.

Mini focus groups created an intimate environment that allowed evaluation of current difficulties in practice. Four premises were discussed (Table 1). Besides the moderator, an observer was present to take field notes. All sessions were audio-recorded. The moderator reviewed the field notes using the audio-files, which were deleted afterwards. Both moderator and observer also summarized their main findings after each session to document first impressions and highlights.

3.3.3. Generative phase

3.3.3.1. *Design studios.* This phase was meant to create concepts of prototypes. The design studio, a popular method in user-centered design [38,39], included sketching and group discussion. It stimulated concept design through brainstorming, design-critique, prioritizing, and iteration (Table A.1.). Because both patients and professionals participated in these rapid iterative workshops that combined divergent and convergent thinking, workshop manners were discussed to empower patients.

3.3.4. Evaluative phase

3.3.4.1. *Think-aloud studies.* The developed prototype was reviewed by patients and professionals in the same manner as other materials had been evaluated at the beginning. However, due to COVID-19, these sessions happened online.

3.3.5. Post-design phase

3.3.5.1. *Evaluation survey.* Six months after implementation, the usefulness of the product was evaluated with a short survey for professionals. This survey was part of a complementary qualitative project, that explored the needs and factors which influence motivation to use BZRA in the treatment of insomnia. Two questions in the survey were of particular interest: one about having used the developed product in practice, the other about their experience with the product.

Table 1
Premises for discussion in mini focus groups, based upon previous literature review and findings from think-aloud studies.

Premises
■ Offering non-pharmacological interventions can only be done by the general practitioner.
■ Currently, we are handling insomnia adequately in primary care.
■ With a leaflet or website of good quality, patients can cope on their own.
■ The already existing material is sufficient.

Table 2

Demographic data of participants (data from earliest phase of participation used if participated in multiple pre-design phases).

	Patients (n = 10)	Healthcare professionals (n = 15)	Survey participants (n = 21)
Age (years)			
Mean (SD)	44.00 (14.73)	41.60 (12.73)	39 (12.54)
Range	24–68	25–60	25–62
Sex, n (%)			
Male	3 (30.00)	7 (46.67)	7 (33.33)
Female	7 (70.00)	8 (53.33)	14 (66.67)

3.4. Analysis

Descriptive statistics were used to summarize demographic data, ISI and HLS-EU-Q16 results. If participants were involved in multiple phases of the project, the first registered demographic data were used. All ISI and HLS-EU-Q16 results were analyzed. Analyses were done with SAS® OnDemand for Academics: SAS® Studio software.

Qualitative content analysis [40,41] for phases 1–3 was done on paper. Two independent researchers coded the data by determining the most important findings separately and discussing them thoroughly. The data were condensed into content categories, based on the frequency of topics and the emphasis put on them by participants. These categories were translated into main findings before continuing to the next phase of the project. Main findings of each phase were discussed with the expert steering committee to assess trustworthiness.

Data from the evaluation survey, collected between 10 and 24 December 2021, were summarized descriptively, using SAS®. Digitally obtained qualitative data were inductively coded with NVivo (released in March 2020) [42] by two independent researchers, and then summarized in a matrix, using the Framework method [43,44]. Some quotes were used to illustrate the findings.

For all qualitative data analysis, any discrepancies were resolved through discussion in team.

4. Results

4.1. Participants

Participants lived across all five provinces in Flanders. Please see Table 2 for more details.

4.1.1. Pre-design, generative and evaluative phases, 1–3

Ten patients and fifteen health professionals from different disciplines participated (Table 3). In each phase, participants with clinical insomnia and problematic or inadequate health literacy were involved (Table 4). Fig. 1 demonstrates how multidisciplinary experts' opinions and patients' perspectives were integrated into each component of the final product, being a modular information leaflet with square cross fold and a separate index card about chronic insomnia and multidisciplinary suggestions for treatment (cfr. Appendix B).

4.1.2. Post-design phase, 4

Thirty professionals requested printed copies of the leaflet to use in practice. Twenty-eight agreed to provide feedback after six months, but only twenty-one completed the survey before the deadline (Table 2). Of the latter, nineteen were unique participants who had not contributed to any of the previous phases.

Table 3

Number of participants in each phase of the project (TAS= think-aloud studies; M-FG=mini focus groups; DS= design studio).

	Pre-design 1.A.TAS	Pre-design 1.B.M-FG	Generative 2. DS	Evaluative 3. TAS	Post-design 4. Evaluation survey
Patient (n = 10)*	6	NA	2	4	NA
General practitioner/MD (n = 4)*	NA	3	2	2	17
Pharmacist (n = 2)*	NA	2	1	1	2
Psychologist/psychiatrist (n = 4)*	NA	3	2	2	2
Physiotherapist (n = 4)*	NA	4	NA	1	NA
Nurse (n = 1)*	NA	1	1	1	NA
Total	6	13	8	11	21

*n represents the total number of unique participants in this category who participated in phases 1–3.

Table 4

Insomnia and health literacy in the co-design participant sample for each phase of the project (TAS= think-aloud studies; M-FG=mini focus groups; DS= design studio).

	1.A. TAS	1.B. M-FG	2. DS	3. TAS
n	6	13	8	11
ISI score				
Mean (SD)	16 (4.23)	6 (4.35)	10 (7.71)	13 (7.72)
Range	9–22	0–15	3–26	2–25
Clinical outcome, n (%)				
No clinically significant insomnia	–	8 (61.54)	4 (50.00)	3 (27.27)
Mild to moderate insomnia	2 (33.33)	4 (30.77)	2 (25.00)	3 (27.27)
Moderate insomnia	3 (50.00)	1 (7.69)	1 (12.50)	4 (36.36)
Severe insomnia	1 (16.67)	–	1 (12.50)	1 (9.09)
HLS-EU-Q16 score				
Mean (SD)	13 (3.08)	15 (1.89)	14 (4.56)	14 (2.81)
Range	9–16	11–16	3–16	8–16
Clinical outcome, n (%)				
Inadequate	–	–	1 (12.50)	1 (9.09)
Problematic	2 (33.33)	3 (23.08)	–	2 (18.18)
Adequate	4 (66.67)	10 (76.92)	7 (87.50)	8 (72.73)



Fig. 1. Summary of the development and implementation process; pre-design phases: 1A and 1B, generative phase: 2, evaluative phase: 3, post-design phase: 4, following the co-design framework of Sanders and Stappers (2014).

4.2. Main findings

Qualitative data from phases 1–3 were integrated for this thematic discussion of the main findings that inspired the final design.

4.2.1. Theme 1: differentiation and patient-centeredness

Patients discussed how materials should focus on specific target groups and differentiate between acute and chronic insomnia. Both patients and professionals emphasized that information about treatment

and referrals should be tailored to the situation of the patient. Moreover, they discussed the importance of differentiating in media: optimally an offline and online information source was developed. Finally, they felt that written material should not stand alone, but could support health-care communication [Tables 5–8](#).

4.2.2. Theme 2: treatment options

Several patients and health professionals highlighted that the commonly used referral “talk to your general practitioner” does not

Table 5

Premises for discussion in mini focus groups, based upon previous literature review and findings from think-aloud studies.

Premises
<ul style="list-style-type: none"> ■ Offering non-pharmacological interventions can only be done by the general practitioner. ■ Currently, we are handling insomnia adequately in primary care. ■ With a leaflet or website of good quality, patients can cope on their own. ■ The already existing material is sufficient.

suffice. Patients preferred more information about treatment options, and what they already could do themselves. Health professionals emphasized the need to engage other disciplines like, for example, psychologists to work on rumination or physiotherapists for physical relaxation training. They emphasized that older patients may need more health care contact, during which sleep problems could be handled multidisciplinary. Nonetheless, most participants recognized the general practitioner as first point of contact in a multidisciplinary network.

4.2.3. Theme 3: sleep diary formats

Keeping a sleep diary was found to be useful to investigate the severity of symptoms and tailor a possible treatment. However, documenting exact hours – of falling asleep or waking up – was deemed very stressful for an insomniac. Patients preferred completing a diary by

estimation, or none at all.

4.2.4. Theme 4: impact matters

Patients noticed that the impact of insomnia on the patient and their context, was not given attention. They felt that this is an important aspect of having insomnia, and that there was no information available about how to cope with, among others, social impact.

4.2.5. Theme 5: language

Patients regularly found scientific jargon, which was found inappropriate. Moreover, some specific words came across as belittling, rude, and even blaming the patient for their current condition. Patients advised to be sensitive to local dialects. Finally, empowerment of the patient was missed when reviewing information about treatment options. Patients preferred more empowering messages and information allowing them to make decisions together with the health professional, also referred to as shared-decision making.

4.2.6. Theme 6: health professional needs

To optimally treat insomnia, health professionals needed an overview of experts for more tailored referrals, more interprofessional communication and feedback on treatment progress, and thorough education of the patient because the importance of sleep was found to be generally underestimated.

Table 6

Demographic data of participants (data from earliest phase of participation used if participated in multiple phases).

	Patients (n = 10)	Healthcare professionals (n = 15)	Survey participants (n = 21)
Age (years)			
Mean (SD)	44.00 (14.73)	41.60 (12.73)	39 (12.54)
Range	24–68	25–60	25–62
Sex, n (%)			
Male	3 (30.00)	7 (46.67)	7 (33.33)
Female	7 (70.00)	8 (53.33)	14 (66.67)

Table 7

Number of participants in each phase of the project (TAS= think-aloud studies; M-FG=mini focus groups; DS= design studio).

	Pre-design 1.A.TAS	Pre-design 1.B.M-FG	Generative 2. DS	Evaluative 3. TAS	Post-design 4. Evaluation survey
Patient (n = 10)*	6	NA	2	4	NA
General practitioner/MD (n = 4)*	NA	3	2	2	17
Pharmacist (n = 2)*	NA	2	1	1	2
Psychologist/psychiatrist (n = 4)*	NA	3	2	2	2
Physiotherapist (n = 4)*	NA	4	NA	1	NA
Nurse (n = 1)*	NA	1	1	1	NA
Total	6	13	8	11	21

*n represents the total number of unique participants in this category who participated in at least one research phase of the project.

Table 8

Insomnia and health literacy in the co-design participant sample for each phase of the project (TAS= think-aloud studies; M-FG=mini focus groups; DS= design studio).

	1.A. TAS	1.B. M-FG	2. DS	3. TAS
n	6	13	8	11
ISI score				
Mean (SD)	16 (4.23)	6 (4.35)	10 (7.71)	13 (7.72)
Range	9–22	0–15	3–26	2–25
Clinical outcome, n (%)				
No clinically significant insomnia	–	8 (61.54)	4 (50.00)	3 (27.27)
Mild to moderate insomnia	2 (33.33)	4 (30.77)	2 (25.00)	3 (27.27)
Moderate insomnia	3 (50.00)	1 (7.69)	1 (12.50)	4 (36.36)
Severe insomnia	1 (16.67)	–	1 (12.50)	1 (9.09)
HLS-EU-Q16 score				
Mean (SD)	13 (3.08)	15 (1.89)	14 (4.56)	14 (2.81)
Range	9–16	11–16	3–16	8–16
Clinical outcome, n (%)				
Inadequate	–	–	1 (12.50)	1 (9.09)
Problematic	2 (33.33)	3 (23.08)	–	2 (18.18)
Adequate	4 (66.67)	10 (76.92)	7 (87.50)	8 (72.73)

4.3. Evaluation of use in practice

Seventeen of twenty-one respondents confirmed that they had used the leaflet in practice and provided feedback. Appendix C shows the final framework matrix with summaries.

4.3.1. Quality

Overall, respondents were pleased with the leaflet. The structure, content, and aesthetics were explicitly praised. The latter was associated with patients taking it home, and triggered reading it.

“Positive: beautifully designed and clear.” (GP5)

4.3.2. Implementation

The leaflet was described as a clear and easy tool to educate patients and support them in their search of help. It was also used to back-up the choice for non-pharmacological treatment.

“[...] The patients are often overloaded with a lot of information in a short time and then written information is always useful to give.” (Phar.2)

“[...] with the aim of educating them and supporting why I chose for a non-pharmacological approach.” (GP13)

One respondent mentioned future implementation, which implies good sustainability of the output. Another respondent used the leaflet in a research project.

4.3.3. Improvement

A colleague of one respondent found that the leaflet contained too much information, and that it was all mixed together. Another professional mentioned that the PDF-version was not well suited for printing.

5. Discussion and conclusion

5.1. Discussion

This project aimed to develop written educational material about insomnia for use in primary care. With the end users as partners, the team developed a relevant leaflet that was positively received in practice. Patient information leaflets have previously been described as useful and needed by both patients and healthcare professionals in primary care [45,46]. Moreover, they have been found to improve patients' knowledge and disease management, doctor-patient communication, patients' intention for screening, and reduce the need for new medical consultations [12–22].

Using different methods in each phase of the co-design process resulted in rich data to inspire product development. Similar to previous studies, patients emphasized readability and design, and commented on visual representation [27,28]. Health professionals focused more on the content and usability. This collaboration resulted in a modular leaflet with separate index card to differentiate between basic information and specifics about chronic insomnia. It offers ample information and multidisciplinary treatment options, which stimulates patient-centered care [47,48]. Although one professional found it contained too much information and another found it difficult to print the leaflet in its current format, overall evaluation was positive after six months of use in practice. The leaflet was found to support non-pharmacological treatment of insomnia and increased self-management by enabling patients to review the evidence-based tips provided by their health professional [49]. Similarly, studies with regard to diabetes, hypertension, and asthma found that improved patients' knowledge and skills empowered them to more actively manage their condition [18,22]. If the leaflet also facilitates health care communication by creating a shared language for patients and professionals, remains to be confirmed.

The project led to two collaborations which increase sustainability of

the results. First, the final leaflet is integrated into a federal online toolkit about insomnia and anxiety for general practitioners and pharmacists. Second, sleep will be added as a major theme on the prevention website of Gezond Leven VZW, a non-profit organization that focuses on education about a healthy lifestyle.

5.1.1. Strengths and limitations

The main strength of this project was the involvement of a multidisciplinary group of professionals and patients with limited health literacy, which resulted in comprehensive information for a wide public with an interesting lay-out. Another strength was the limited number of participants in the focus groups, which allowed us to discuss difficult topics more in-depth while paying attention to individual sensitivities. Methodologically, the project was strengthened by the framework of Sanders and Stappers [32], and the multidisciplinary experts' steering committee.

Like in many projects, there were several limitations. Project finances interfered with creating an online tool. More networking and time for recruitment, could have increased patient involvement. Although data was found to be adequate, with main findings being repeated by participants both within as across phases, final sample sizes were steered by pragmatic considerations. Furthermore, the leaflet is only available in Dutch. Adaptation to other languages and cultures could be relevant. Finally, using field notes instead of ad verbatim transcriptions could be a methodological limitation, although summarized findings were verified by experts throughout the project.

6. Conclusion

This co-design project led to an educational leaflet that was well received in practice. It increased our understanding of how patients want to receive information about sleep and insomnia in primary care. Written information supports patient education, but cannot stand alone. Differentiation in content and visual design play an important role. Finally, the project confirmed the added value of participatory research when designing educational healthcare products.

Practice implications

Supporting patients when confronted with sleeping disorders is an important task for primary care professionals, which has become even more relevant in light of the COVID-19 pandemic. This project led to an information leaflet that facilitates patient education and treatment of insomnia with non-pharmacological interventions, and increases self-management skills of patients. Ideally, the leaflet is used in a multifaceted intervention with tailored patient education or in shared-decision making processes. Future projects should assess if the leaflet also facilitates health care communication.

Funding

This work was supported by ebpracticenet, the Belgian platform for Evidence Based Practice in healthcare, Belgium (credit nr. ZL31230600-702).

Informed consent and participants' details

In September 2019, approval of the Ethics Committee Research UZ/KU Leuven was obtained for the pre-design, generative and evaluative phase. (reference: S63037). The post-design evaluation, a survey, was part of a complementary qualitative project, for which approval was obtained from the Social and Societal Ethics Committee in August 2021 (reference: G-2021-3713-R2(MAR)). I confirm all patient/personal identifiers have been removed or disguised so the patient/person(s) described are not identifiable and cannot be identified through the details of the story.

CRedit authorship contribution statement

Kristien Coteur: Conceptualization; Formal analysis; Funding acquisition; Investigation; Methodology; Project administration; Resources; Software; Supervision; Validation; Visualization; Writing - original draft. **Catharina Matheï:** Conceptualization; Funding acquisition; Methodology; Project administration; Supervision. **Marc Van Nuland:** Conceptualization; Supervision; Formal analysis; Writing - review & editing. **Birgitte Schoenmakers:** Writing - review & editing.

Declaration of Competing Interest

None.

Acknowledgements

Thanks to all members of the multidisciplinary steering committee who provided valuable insights and expert opinions during the project: psychologists prof. em. Jo Goedhuys, Annelore Roose; pharmacists prof. Veerle Foulon, prof. Marc Naegels, Bart Kerre; geriatrist prof. dr. Jos Tournoy; general practitioners prof. dr. Marc Van Nuland, prof. dr. Catharina Matheï; implementation specialist Julie Cristens; federal representative Nele Van Tomme; and patient Anne-Marie Nolevaux. Thank you Lore Raets and Shani De Coster for helping with data collection and analysis. The professional writing sessions with Farida Barki at Wablift contributed to creating accessible content. Amis d'Emile, also known as Lisa Van der Auwera, beautifully designed and illustrated the leaflet. A special thank you to all participants for your valuable contribution. Finally, this work could not have been accomplished without the funding of EBPracticenet, the Belgian reference platform for Evidence Based Practice in healthcare (credit nr. ZL31230600-702).

SAS and all other SAS Institute Inc. product or service names are registered trademarks or trademarks of SAS Institute Inc. in the USA and other countries. ® indicates USA registration.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at [doi:10.1016/j.pec.2022.08.018](https://doi.org/10.1016/j.pec.2022.08.018).

References

- [1] NIH State of the Science. Conference statement on manifestations and management of chronic insomnia in adults [conference statement]. *NIH Consens State—Sci Statements* 2005;22:1–30.
- [2] Nowicki Z, Grabowski K, Cubala WJ, Nowicka-Sauer K, Zdrojewski T, Rutkowski M, Bandosz P. Prevalence of self-reported insomnia in general population of Poland. *Psychiatr Pol* 2016;50:165–73.
- [3] Ohayon MM, Lemoine P. A connection between insomnia and psychiatric disorders in the French general population. *Encephale* 2002;28:420–8.
- [4] Rocha FL, Guerra HL, Lima-Costa MF. Prevalence of insomnia and associated sociodemographic factors in a Brazilian community: the Bambui study. *Sleep Med* 2002;3:121–6.
- [5] Gisle L, Drieskens S, Demarest S, Van der Heyden J. Geestelijke gezondheid: gezondheidsenquête 2018. [Mental health: health interview survey 2018]. Sciensano (Belgium);2019. Report number: D/2020/14.440/4. Available from: (https://his.wiv-isp.be/nl/Gedeelde%20%20documenten/MH_NL_2018.pdf).
- [6] Achste COVID-19-Gezondheidsenquête. Eerste resultaten. [Eight COVID-19 Health Interview Survey. First results.] Brussels, Belgium; Depot number: D/2021/14.440/81. Available from: (<https://doi.org/10.25608/vndz-xc17>).
- [7] Medicines management programme. Guidance on appropriate prescribing of benzodiazepines and z-drugs (BZRA) in the treatment of anxiety and insomnia. Online: HSE; February 2018. 53 p. Report version 1.0. Retrieved from (<https://www.hse.ie/eng/about/who/cspd/ncps/medicines-management/bzra-for-anxiety-insomnia/bzraguidancemmpfeb18.pdf>) on 21 October 2020.
- [8] Cloetens H, Declercq T, Habraken H, Callens J, Van Gastel A. Aanpak van slaapklaften en insomnie bij volwassenen in de eerste lijn. Herziening (versie 28/06/2018). [Treatment of sleep complaints and insomnia in adults in primary care. Revision (version 28/06/2018).] Online: EBPracticenet; 30 June 2018. 82 p.
- [9] Mitchell MD, Gerhrman P, Perlis M, Umscheid CA. Comparative effectiveness of cognitive behavioral therapy for insomnia: a systematic review. *BMC Fam Pract* 2012;13:1–11.
- [10] Bashir K, King M, Ashworth M. Controlled evaluation of brief intervention by general practitioners to reduce chronic use of benzodiazepines. *Br J Gen Pr* 1994;44:408–12.
- [11] Kuntz JL, Kouch L, Christian D, Hu W, Peterson PL. Patient education and pharmacist consultation influence on nonbenzodiazepine sedative medication deprescribing success for older adults. *Perm J* 2019;23:18–161.
- [12] Grime J, Blenkinsopp A, Raynor DK, Pollock K, Knapp P. The role and value of written information for patients about individual medicines: a systematic review. *Health Expect* 2007;10:286–9.
- [13] Johnson A, Sandford J, Tyndall J. Written and verbal information versus verbal information only for patients being discharged from acute hospital setting to home. *Cochrane Database Syst Rev*, 4; 2003. p. 1–21.
- [14] Morris LA, Mazis M, Gordon E. A survey of the effects of oral contraceptive patient information. *JAMA* 1977;238:2504–8.
- [15] Raynor DK, Savage I, Knapp P, Henley J. We are the experts: people with asthma talk about their medicine information needs. *Patient Educ Couns* 2004;53:167–74.
- [16] Raynor DK, Knapp P. Do patients see, read and retain the new mandatory medicines information leaflets? *Pharm J* 2000;264:268–70.
- [17] Thompson S, Stewart K. Older persons' opinions about, and sources of, prescription drug information. *Int J Pharm Pr* 2001;9:153–62.
- [18] Vooradi S, Acharya LD, Seshadri S, Thunga G, Vijayanarayana K. Preparation, validation and user-testing of patient information leaflets on diabetes and hypertension. *Indian J Pharm Sci* 2018;80:118–25. <https://doi.org/10.4172/pharmaceutical-sciences.1000336>.
- [19] Jarernsiripornkul N, Phueanpinit P, Pongwecharak J, Krska J. Development and evaluation of user-tested Thai patient information leaflets for non-steroidal anti-inflammatory drugs: effect on patients' knowledge. *PLoS One* 2019;14:e0210395. <https://doi.org/10.1371/journal.pone.0210395>.
- [20] Humphris G, Field E. The immediate effect on knowledge, attitudes and intentions in primary care attenders of a patient information leaflet: a randomized control trial replication and extension. *Br Dent J* 2003;194:683–8. <https://doi.org/10.1038/sj.bdj.4810283>.
- [21] Sustersic M, Tissot M, Tyrant J, et al. Impact of patient information leaflets on doctor–patient communication in the context of acute conditions: a prospective, controlled, before–after study in two French emergency departments. *BMJ Open* 2019;9:e024184. <https://doi.org/10.1136/bmjopen-2018-024184>.
- [22] Kovacevic M, Culafic M, Jovanovic M, Vucicevic K, Kovacevic SV, Miljkovic B. Impact of community pharmacists' interventions on asthma self-management care. *Res Soc Adm Pharm* 2018;14:603–11. <https://doi.org/10.1016/j.sapharm.2017.07.007>.
- [23] Fajardo MA, Weir KR, Bonner C, Gjindic D, Jansen J. Availability and readability of patient education materials for deprescribing: an environmental scan. *Br J Clin Pharm* 2019;85:1396–406. <https://doi.org/10.1111/bcp.13912>.
- [24] Beagley L. Educating patients: understanding barriers, learning styles, and teaching techniques. *J Perianesth Nurs* 2011;26:331–7. <https://doi.org/10.1016/j.jopan.2011.06.002>.
- [25] Coulter A, Ellins J. Effectiveness of strategies for informing, educating, and involving patients. *BMJ* 2007;7:24–7.
- [26] Van Beusekom MM, Grootens-Wiegers P, Bos MJW, Guchelaar H-J, van den Broek JM. Low literacy and written drug information: information-seeking, leaflet evaluation and preferences, and roles for images. *Int J Clin Pharm* 2016;38:1372–9. <https://doi.org/10.1007/s11096-016-0376-4>.
- [27] Fagerlin A, Lakhani I, Lantz PM, Janz NK, Morrow M, Schwartz K, et al. An informed decision? Breast cancer patients and their knowledge about treatment. *Patient Educ Couns* 2006;64:303–12. <https://doi.org/10.1016/j.pec.2006.03.010>.
- [28] Schillinger D, Machinger EL, Wang F, Palacios J, Rodriguez M, Bindman A. Language, literacy, and communication regarding medication in an anticoagulation clinic: a comparison of verbal vs. visual assessment. *J Health Commun* 2006;11:651–64. <https://doi.org/10.1080/10810730600934500>.
- [29] Federal public service for health, food chain safety and environment. Slaap- en kalmeermiddelen, denk eerst aan andere oplossingen [Hypnotics and sedatives, first think of other solutions] [leaflet]. 2018. Available from: (https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/spf-brochure-triptyque-a5-nl-hd.pdf).
- [30] Mercer SW, O'Brien R, Fitzpatrick B, Higgins M, Guthrie B, Watt G, et al. The development and optimisation of a primary care-based whole system complex intervention (CARE plus) for patients with multimorbidity living in areas of high socioeconomic deprivation. *Chronic Illn* 2016;12:165–81. <https://doi.org/10.1177/1742395316644304>.
- [31] Tistad M, Lundell S, Wiklund M, Nyberg A, Holmner A, Wadell K. Usefulness and relevance of an health tool in supporting the self-management of chronic obstructive pulmonary disease: explorative qualitative study of a cocreative process. *JMIR Hum Factors* 2018;5:e10801.
- [32] Sanders EB-N, Stappers PJ. Probes, toolkits and prototypes: three approaches to making in codesigning. *CoDesign* 2014;10:5–14. 10.180/15710882.2014.888183.
- [33] Sheridan S, Halpern D, Viera A, Berkman N, Donahue K, Crotty K. Interventions for individuals with low health literacy: a systematic review. *J Health Commun* 2011;16:30–54.
- [34] Morin CM, Belleville G, Bélanger L, Ivers H. The Insomnia Severity Index: psychometric indicators to detect insomnia cases and evaluate treatment response. *Sleep* 2011;34:601–8. <https://doi.org/10.1093/sleep/34.5.601>.
- [35] Sørensen K, Van den Broucke S, Pelikan JM, Fullam J, Doyle G, Slonska Z, et al. Measuring health literacy in populations: illuminating the design and development process of the European Health Literacy Survey Questionnaire (HLS-EU-Q). *BMC Public Health* 2013;13:948.

- [36] Eccles DW, Arsal G. The think aloud method: what is it and how do I use it. *Qual Res Sport Exerc Health* 2017;9:514–31. <https://doi.org/10.1080/2159676X.2017.1331501>.
- [37] Jaspers MWM, Steen T, van den Bos C, Geenen M. The think aloud method: a guide to user interface design. *Int J Med Inf* 2004;73:781–95. <https://doi.org/10.1016/j.ijmedinf.2004.08.003>.
- [38] Ungar J.M., White J.A. Agile User Centered Design: Enter the Design Studio - A Case Study. *Proceedings of CHI 2008*; 2008 Apr 5–10; Florence, Italy. doi: [10.1145/1358628.1358650](https://doi.org/10.1145/1358628.1358650).
- [39] Kaplan K. Facilitating an Effective Design Studio Workshop [Internet]. Nielsen Norman Group: World Leaders in Research-Based User Experience; 2017 [cited 2022 Jan 4]. Available from: <https://www.nngroup.com/articles/facilitating-design-studio-workshop/>.
- [40] Mayring P. Qualitative content analysis: theoretical foundation, basic procedures and software solution. Austria, Klagenfurt; 2014 [cited 2022 Jan 4]. Available from: https://www.ssoar.info/ssoar/bitstream/handle/document/39517/ssoar-2014-mayring-Qualitative_content_analysis_theoretical_foundation.pdf.
- [41] Graneheim UH, Lindgren BM, Lundman B. Methodological challenges in qualitative content analysis: a discussion paper. *Nurse Educ Today* 2017;56:29–34. <https://doi.org/10.1016/j.nedt.2017.06.002>.
- [42] QSR International Pty Ltd. (2020) NVivo (released in March 2020), (<https://www.qsrinternational.com/nvivo-qualitative-data-analysis-software/home>).
- [43] Nowell LS, Norris JM, White DE, Moules NJ. Thematic analysis: striving to meet the trustworthiness criteria. *Int J Qual Methods* 2017;16:1–13. <https://doi.org/10.1177/1609406917733847>.
- [44] Gale NK, Heath G, Cameron E, Rashid S, Redwood S. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC Med Res Method* 2013;13(1):117.
- [45] O'Connor R, O'Doherty J, O'Regan A, et al. Antibiotic use for acute respiratory tract infections (ARTI) in primary care; what factors affect prescribing and why is it important? A narrative review. *Ir J Med Sci* 2018;187:969–86. <https://doi.org/10.1007/s11845-018-1774-5>.
- [46] Mahon B, Sides E, Allison R, Lecky DM, McNulty CAM. Empowering patients to self-manage common infections: Qualitative study informing the development of an evidence-based patient information leaflet. *Antibiotics* 2021;10:1113. <https://doi.org/10.3390/antibiotics10091113>.
- [47] Moore L, Britten N, Lydahl D, Naldemirci Ö, Elam M, Wolf A. Barriers and facilitators to the implementation of person-centred care in different healthcare contexts. *Scand J Caring Sci* 2016;31:662–73. <https://doi.org/10.1111/scs.12376>.
- [48] Luxford K, Safran DG, Delbanco T. Promoting patient-centered care: a qualitative study of facilitators and barriers in healthcare organizations with a reputation for improving the patient experience. *Int J Qual Health Care* 2011;23:510–5. <https://doi.org/10.1093/intqhc/mzr024>.
- [49] Adams K, Greiner AC, Corrigan JM. Chapter 5: patient self-management support. In: Adams K, Greiner AC, Corrigan JM, editors. *Institute of Medicine (US) Committee on the Crossing the Quality Chasm: Next Steps Toward a New Health Care System*. Washington DC, USA: National Academies Press; 2004. p. 57–66.