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

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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 Sassett. 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].

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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 (CBT-I), 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.                           |
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 2
Demographic data of participants (data from earliest phase of participation used if participated in multiple pre-design phases).

| Age (years) | Patients (n = 10) | Healthcare professionals (n = 15) | Survey participants (n = 21) |
|------------|-----------------|---------------------------------|-----------------------------|
| 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 3
Number of participants in each phase of the project (TAS= think-aloud studies; M-FG=mini focus groups; DS= design studio).

| Patient (n = 10)* | Pre-design 1.A.TAS | Pre-design 1.B.M-FG | Generative 2. DS | Evaluative 3. TAS | Post-design 4. Evaluation survey |
|-------------------|--------------------|---------------------|------------------|-------------------|----------------------------------|
| 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        |           |       |        |
| 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) |
4.2. 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 healthcare 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...
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.
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.

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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: 563037). 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.
Declaration of Competing Interest

None.

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Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.jpec.2022.08.018.

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