




Developing and Validating a Parent Guide to Improve Sleep in Children with Autism Spectrum Disorder: Emphasis on the Holistic Approach to Self-Regulation Strategies

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Abstract

Background: Autism spectrum disorder (ASD) frequently coexists with sleep problems. This study, guided by family-centered and general systems theories and acknowledging the reciprocal relationships between sleep and self-regulation, details the process of designing a parent guide aimed at improving sleep in children aged 6–12 years diagnosed with level 1 or 2 ASD.

Methods: A literature search was conducted to identify interventions that emphasize self-regulation strategies aimed at improving children's sleep. The content and face validity of this guide were evaluated based on the opinions of experts and parents. In a pilot study, the guide was presented to parents of children with ASD ($n = 3$) in the form of a booklet, and its effectiveness was assessed through caregiver feedback and the Children's Sleep Habits Questionnaire (CSHQ).

Results: The booklet comprises 23 subtitles organized into four chapters: "Introductory Information," "Child-Related Factors," "Environment-Related Factors," and "Impact of Other Activities on Sleep." In this feasibility pilot ($n=3$), minor reductions (2–3 points) in CSHQ scores were observed; however, this magnitude of change is below typical minimal clinically important differences, and the study was not designed to assess efficacy.

Conclusion: The development of a parent guide for sleep of children with ASD was driven by the need to address self-regulatory strategies across three interrelated dimensions: the child, the environment, and sleep itself. This approach is superior to single-domain interventions that do not adequately consider the complex interplay of self-regulation deficits in ASD. This study provides initial evidence for the viability and promise of this intervention, paving the way for definitive future trials.

Keywords: Autism Spectrum Disorder, Self-Regulation, Emotion Regulation, Sleep, Parents, Caregivers, Booklets

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Introduction

Sleep disturbances affect up to 80% of children with Autism Spectrum Disorder (ASD), with a higher prevalence observed among those aged 6–12 years and those diagnosed with ASD levels 1–2, who require support or substantial support (1). These disturbances are associated with adverse outcomes across multiple domains, including cognitive functioning—particularly attention and memory—emotional regulation, social behavior, pain sensitivity, and

heightened sensory reactivity, which may exacerbate repetitive behaviors (2–7). This situation necessitates targeted interventions for these groups. Furthermore, sleep disturbances can contribute to increased parental stress and disrupted sleep patterns among caregivers (8, 9).

A bidirectional relationship exists between sleep and self-regulation, characterized by the complex interplay between the prefrontal cortex (PFC) and the anterior cingulate

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↑What is “already known” in this topic:

Despite the high prevalence of sleep disorders in children with ASD, existing research often lacks a comprehensive perspective that integrates the sensory, emotional, mental, physical, and social dimensions of self-regulation.

→What this article adds:

We developed and validated a system-oriented parent guide aimed at improving sleep in children with ASD. This guide was deemed acceptable and feasible for use by parents in the child's real-life environment.

cortex (10). Self-regulation—defined as the processes by which the central nervous system (CNS) manages its internal states and adapts to environmental demands (11)—is critically dependent on the PFC. This brain region exhibits a high metabolic rate during wakefulness, which decreases during rest. Consistent with this, electroencephalography (EEG) studies confirm the PFC's pivotal role in regulating both sleep quality and self-regulatory functions (12).

Given the individual variability in self-regulation abilities, differences in connectivity within regions such as the prefrontal cortex (PFC) are likely to contribute to variations in rapid eye movement (REM) sleep (13), non-rapid eye movement (NREM) sleep, sleep patterns, and overall sleep quality (10). In individuals with ASD, self-regulation deficits—such as sensory hypersensitivity and emotional dysregulation (e.g., anxiety)—further disrupt sleep initiation and maintenance by increasing arousal and delaying REM onset (14).

This study is conceptually grounded in the integration of two complementary theoretical frameworks: the "family-centered paradigm" (15, 16) and "general systems theory" (17).

The family-centered paradigm serves as the foundational pillar for empowering parents, positioning them as central agents of change in the intervention process. The child's sleep problem is prioritized from the family's perspective, and the family is actively involved in selecting and implementing the most appropriate strategies at home. These elements are key criteria of the family-centered paradigm (18).

Concurrent with this, general systems theory provided an overarching architectural framework that mandates a holistic perspective, transcending a reductionist focus on the child in isolation. It explicitly guided the systematic integration of the child's internal factors (e.g., sensory processing, arousal), the environmental context (e.g., bedtime routines, sensory milieu), and the multifaceted nature of sleep itself (15, 19). This synergistic application of both theories ensured the development of a comprehensive intervention that acknowledges and addresses the complex, dynamic, and reciprocal interactions among these systems (20, 21).

Self-regulation in autism is a multidimensional construct that encompasses physical, sensory, cognitive, emotional, and social domains (22). It is significantly associated with sleep. However, existing interventions, such as melatonin supplementation or behavioral sleep training, tend to target only single domains, thereby neglecting the interplay of sensory, emotional, and environmental factors that are critical for improving sleep in individuals with ASD (23-30).

This study aimed to develop and validate the 'Parent Guide,' a novel intervention designed to address a critical gap in available resources. The guide provides a system-oriented, self-regulation-based protocol for managing sleep problems in individuals with ASD, specifically tailored for home implementation by parents.

Methods

Study Design

This study aimed to develop and validate a parent guide for sleep of children with ASD as part of a clinical trial (ID: IRCT20240105060616N1). To ensure adequate reporting, the authors adhered to the TIDieR (Template for Intervention Description and Replication) reporting guideline, which is an extension of the Consolidated Standards of Reporting Trials (CONSORT) (Appendix 1). The development and validation of the sleep guide occurred in three phases (Appendix 2):

Phase 1: Development of Intervention Strategies

An exploratory narrative review of the literature was conducted, guided by a predefined search strategy (Appendix 3), focusing on self-regulation and sleep in children. The first author searched databases including PubMed, ScienceDirect, Cochrane Library, Otseeker, Google Scholar, Magiran, SID, and Irandoc for relevant studies. Studies were included if they were clinical trials involving a pediatric population from 2000 to 2024. Exclusion criteria encompassed studies published in languages other than Persian or English, review articles, interventions involving pharmacological or technological approaches, and studies employing correlational designs. Given that the intervention was intended to be implemented by families, we prioritized selecting approaches with the strongest empirical support. Correlational studies were excluded because they do not establish causality and thus provide limited guidance for intervention design. Technological interventions were also omitted due to several constraints: their high cost, which would render them inaccessible for most families; the inability of the research budget to cover such expenses for all participants; and the fact that children with ASD often require extensive time and support to adapt to technology-based tools. Consequently, technology-dependent studies were not considered for inclusion. The review identified self-regulation strategies that demonstrated effectiveness in improving sleep outcomes in children (24, 31-34).

Mapping the relationship between theoretical frameworks and intervention strategies.

This study is grounded in the complementary integration of two major theoretical perspectives: the family-centered paradigm and general systems theory (17). Together, these frameworks informed both the overarching philosophy and structural design of the intervention, while multidimensional self-regulation theory guided the development of its specific techniques and content.

The family-centered paradigm served as the fundamental ethical and practical guide for the intervention (15, 16). It emphasizes that parents should not be regarded as passive recipients of professional guidance; instead, they are knowledgeable authorities on their child and the primary agents of change. This principle is directly reflected in several components of the intervention: (a) the manual is designed to support parent-directed implementation within the home setting; (b) it employs clear language and adaptable methods, allowing parents to customize strategies according to their child's characteristics and their family's

circumstances; and (c) it focuses on sleep challenges as identified and prioritized by the family itself (18).

Second, general systems theory served as the primary structural framework for designing a comprehensive and integrative intervention (17). This perspective required us to conceptualize sleep not as an isolated phenomenon but as emerging from a fluid interplay among multiple interdependent subsystems. Guided by this theory, we organized the parent guide into four interconnected chapters, each representing a key subsystem: (1) the child's internal system (e.g., sensory processing, emotional arousal), (2) the environmental system (e.g., bedtime routines, sensory characteristics of the sleep environment), (3) the temporal/activity system (e.g., the influence of daytime activities on sleep readiness), and (4) an introductory section clarifying how these systems interact. This layout facilitates intervention planning that acknowledges reciprocal influences—such as the relationship between a child's sensory hyperresponsivity (child system) and bedroom noise or lighting (environmental system) (19, 20).

The content integrated into this systems-based structure was directly informed by the general multidimensional theory of self-regulation (22). In ASD, self-regulation challenges span physical, sensory, cognitive, emotional, and social domains, each of which influences and is influenced by sleep. Consequently, our guide refrains from providing generalized sleep hygiene advice. The strategies were selected based on the integration of three key theoretical frameworks of self-regulation in occupational therapy: the Synactive Developmental Theory, Sensory Integration Theory, and Cognitive Behavioral Theory. Each framework informed specific components of the intervention (35). Drawing from the Synactive Theory, which recognizes that children with ASD often exhibit immature or dysregulated autonomic nervous system functions, the intervention incorporated strategies to support the gradual stabilization of physiological states. These strategies included creating a calming and predictable bedtime environment, as well as employing techniques such as paced sensory input and caregiver-infant interaction patterns to promote neural integration and regulation. Additionally, the intervention embedded sensory modulation techniques derived from Sensory Integration Theory to address atypical sensory processing. For instance, the strategies included the controlled use of deep pressure touch and massage, minimizing exposure to disruptive sensory stimuli (e.g., bright lights, loud noises), and utilizing auditory masking tools (e.g., white noise) to help modulate arousal levels. Furthermore, the intervention integrated behavioral components targeting sleep-related anxiety and maladaptive behaviors from Cognitive Behavioral Theory; these included training children in relaxation techniques (e.g., yoga), establishing consistent bedtime routines, and employing positive reinforcement to encourage sleep-promoting behaviors.

In summary, we developed the Parent Guide by integrating the parent-empowerment principles of family-centered care with the comprehensive perspective provided by systems theory, while embedding domain-specific self-regulation strategies within this framework.

Phase 2: Preparing the Booklet

To address the complex interactions among the child, the environment, and sleep, the findings from the literature review were analyzed using the International Classification of Functioning, Disability and Health (ICF) framework. Consequently, the intervention incorporated factors related to body functions (e.g., sensory processing), environmental influences (including physical modifications to the bedroom, social factors, and attitudinal aspects), as well as sleep preparation and participation, which encompassed sleep patterns, habits, routines, and rituals (36, 37).

Content validity: To assess content validity, two expert panel sessions, each lasting two hours, were conducted with a multidisciplinary team comprising three child psychiatrists, one child psychologist, and four occupational therapists, all of whom have a minimum of ten years of experience in therapy and research related to ASD.

Face validity was established through feedback from a panel of experts and three primary caregivers of children with ASD, who reviewed the booklet for relevance and clarity. This process resulted in specific revisions, ensuring that the content was both scientifically sound and practically applicable to the target population.

Phase 3: Piloting the Booklet

Four children aged 6 to 12 years, diagnosed with level 1 or 2 ASD according to the DSM-5 criteria, were selected for the study. These children scored above 41 on the Children's Sleep Habits Questionnaire (CSHQ), indicating significant sleep disturbances. Inclusion criteria required that each child have a literate primary caregiver capable of participating in reading booklets and educational activities, and that they implement the intervention. None of the children were taking sleep-inducing medications. Additionally, parents had to identify sleep disturbances as a primary concern. Written informed consent was obtained from all participating parents. Verbal consent was also sought from the children, provided they had adequate communication skills and comprehension. Initially, it was planned that verbal assent would be obtained from participating children with sufficient communication abilities. For instance, the therapist would show the child illustrations from the booklet and inquire whether they were willing to engage in the depicted activities. If the child understood the therapist's simple explanations and could verbally communicate agreement or disagreement, their consent would be considered as assent. This verbal assent was recorded in the research project file after obtaining written consent from the parents.

An eight-week intervention was conducted, which included a pretest and posttest of the CSHQ. Caregivers' feedback during the intervention was systematically analyzed and integrated into the revision of the booklet through a structured process. First, qualitative data were collected from pilot phase logbooks, open-ended survey responses, and discussion sessions with parents. This feedback was then analyzed to identify and categorize key themes, challenges, and suggestions, such as the need for greater activity variety and difficulties with transitions.

Measures

After confirming eligibility according to the inclusion and exclusion criteria, we employed five instruments to collect the foundational information necessary for developing the booklet:

1. Children's Sleep Habits Questionnaire (CSHQ) (38): It was used as both a pretest and posttest. Prior to the intervention, baseline sleep was assessed using the CSHQ. Each parent received individualized training tailored to their child's CSHQ profile, addressing specific deficits in sleep quality and quantity. The CSHQ was chosen for its demonstrated reliability in measuring sleep disturbances in children with ASD, with a Cronbach's alpha of 0.83 and an intraclass correlation coefficient (ICC) for test-retest reliability of 0.90 (39).

2. Short Sensory Profile - 2 (SSP-2) (40): This assessment was administered prior to the intervention. The results were utilized to identify each child's specific sensory needs, allowing for the individualization of the intervention by selecting the most appropriate strategies from the accompanying booklet.

3. Child and Adolescent Sleeping Environment Scale (CASES) (41): Before the intervention, we conducted this assessment to identify the necessary modifications to the child's-bedroom environment.

4. Measure of Process of Care - 20 (MPOC-20) (42): This instrument was administered to parents to systematically assess their perceptions and satisfaction regarding the intervention.

5. Sleep diary (43): This tool was utilized to prospectively monitor the child's sleep patterns, including key parameters such as sleep onset latency, night awakenings, and total sleep duration.

Intervention

Material: The sleep guide, along with the materials necessary for implementing the strategies at home, was provided to the parents. Additionally, in-person training sessions were conducted at clinic, with refreshments supplied by the research team to ensure that parents faced no financial or time burden.

Procedure: The content of the booklet was presented to parents over an eight-week period through 4-5 face-to-face sessions, each lasting 30-60 minutes, either in the clinic or via phone by the first author. This approach aimed to empower parents to utilize the booklet at home (13, 24, 26). Recognizing that not all sensory strategies were suitable for every child—due to variations in sensory processing patterns such as sensory seeking, sensory avoidance, low registration, and sensory sensitivity (44, 45)—the therapist tailored the selection of strategies according to each child's SSP-2 results (see Appendix 4). Caregivers were instructed to adjust the intensity and duration of each strategy based on their child's individual reactions to sensory input. Modifications to the bedroom environment were implemented based on the CASES, including adjustments to cleanliness, noise levels, room lighting, temperature, the presence of electronic devices, and the type of blanket, sheet, or pillow used. Other strategies were applied according to the child's

specific issues identified in the CSHQ and their level of cooperation and interest in the booklet activities. Thus, individualized training was provided based on the scores from the SSP-2, the pre-test CSHQ, and the CASES.

The first author assessed parental adherence to treatment using a logbook, in which parents recorded the strategies implemented at home on a daily basis. These records were reviewed weekly by the research team to monitor compliance. Non-adherence was defined as the failure to implement at least 70% of the prescribed strategies for more than one week. The number of strategies presented in the various sections of the booklet (sensory, behavioral, environmental, etc.) varied across topics. Prior to the intervention, the therapist documented individualized and guided activities for parents in each child's personal logbook. According to the daily logbook reviews, three parents completed at least two-thirds of the assigned activities (approximately 70%), while one participant was excluded from the study. The 70% adherence threshold was established a priori to balance scientific rigor with practical feasibility in a home-based setting (46). This benchmark was designed to ensure that participants received a sufficient dose of the core intervention components, allowing for a fair evaluation of its effects—a key consideration for intervention fidelity. Perfect (100%) adherence is often unrealistic in home-based interventions.

If the logbook and sleep diary images were not received by noon the following day, the therapist sent a text reminder, allowing the parents the opportunity to complete and submit them that evening. If the submissions were not received by the evening following the reminder, the therapist contacted the parents via a brief phone call. During this call, a semi-structured interview was conducted, addressing the diary topics, which included the time of going to bed, time of waking, number of nighttime awakenings, overall sleep quality, and specific events affecting sleep, as well as the activities assigned to the child. The therapist immediately recorded the parents' responses in an electronic file derived from the same logbook and diary.

Results

The purpose of this study was confined to the design and primary validation of the booklet using a very small sample size, rather than evaluating its effectiveness. Consequently, comprehensive statistical analyses, including effect sizes and other relevant parameters, were not conducted, as the study was not adequately powered to assess effectiveness.

Phase 1: Development of Intervention Strategies

A total of 262 studies and 3 guidelines were identified during the literature search. Of these, 224 studies were excluded, resulting in 38 studies selected for further evaluation (see Figure 1 and Appendix 5).

The interventions identified in the reviewed literature included behavioral strategies (n = 20), sensory-based strategies (n = 12), yoga (n = 2), and emotion regulation strategies (n = 1). The sensory-based category comprised massage (n = 9), sensory integration therapy (n = 2), and sand play therapy (n = 1).

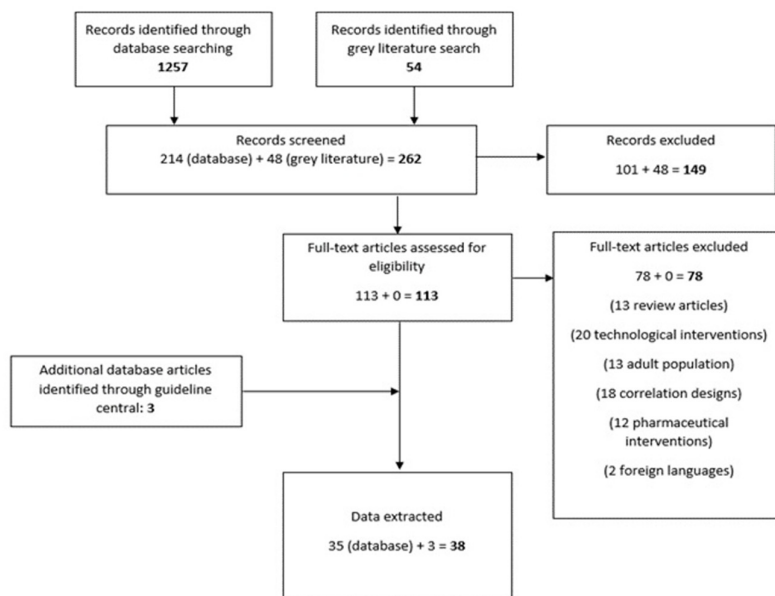


Figure 1. Process of data extraction for generating booklet content

Phase 2: Preparing the Booklet

The booklet was created based on a thorough literature review and contributions from families and experts (see Appendix 6).

The booklet was ultimately organized into four chapters: 'Introduction' (3 titles), 'Child-Related Factors' (4 titles, 18 subtitles), 'Environment-Related Factors' (2 titles), and 'Impact of Other Activities on Sleep' (2 titles) (Table 1).

Phase 3: Piloting the Booklet

On average, the total CSHQ scores of the three participants exhibited a slight decrease of 2–3 points, while the mean sleep duration increased by 15.6 minutes (Table 2). Although these preliminary changes do not imply efficacy, they indicate that the intervention procedures were feasible and well tolerated by both the participants and their families.

Daily reviews of the logbooks and sleep diaries indicated that effective implementation of the intervention resulted in the regulation of sleep patterns that night.

The MPOC-20 results indicated that parents were satisfied with the ease of use of the booklet content, the guidance provided by therapists, and the home implementation process, all of which contributed to the acceptance of the intervention.

Based on the records from the intervention provider, parents reported various practical challenges and preferences during the intervention, which were documented in their direct qualitative feedback:

- Participants displayed disinterest in both music and mandala coloring. One mother reported, "My son immediately covered his ears when we played the relaxation music. He said, 'I don't like it,' and refused to listen." Another parent remarked, "The mandala was not appealing to my daughter; she only colored one corner of it and said it

wasn't pretty."—Consequently, a greater variety of music and mandalas was provided, and it was recommended that parents respect their child's preferences.

- The child struggled to complete puzzles. A mother explained, "The first puzzle was too difficult and led to a meltdown. He couldn't find the pieces and became incredibly frustrated before bed, which was the opposite of what we intended." Consequently, a variety of puzzles with differing levels of complexity were provided to better match the child's challenge level.

- Parents experienced difficulty transitioning to the next step of the bedtime routine. One parent remarked, "Moving from the toilet to pajamas was a battle. He would run away and hide. We didn't know how to make the transition smoother without yelling." Consequently, a related behavioral technique was incorporated into the training content.

- The parents did not engage in massage during the first two weeks, and the mother reported, "Every time I tried to massage him, he would stiffen up or push my hands away. We felt like we were forcing him and almost gave up." They were advised to be patient and continue, as this reaction is normal.

Additionally, some parents encountered financial and time constraints that hindered their ability to prepare the necessary supplies. Certain sensory strategies were costly; for instance, purchasing a swing, a white-noise machine, or items such as Epsom bath salt and multiple puzzles led to the consideration of lower-cost alternatives. Examples of these alternatives included using a rocking chair instead of a swing, recording white-noise sounds to play through the parents' phone at night, preparing multi-shape puzzles and completing one shape each night, and purchasing bath salts in installments from a familiar supplier. Furthermore, performing all 12 steps of the sleep massage each night proved to be time-consuming for the parents. To address this, a

Table 1. Content of the booklet

Chapter	Title: - Subtitle
Introduction	Autism spectrum disorder, core symptoms and problems Sleep problems in children with autism Relationship between sleep and self-regulation
Child-related factors	Behavioral strategies for children's sleep: - A Guide to sleep hygiene - Extinction - Graded Extinction - Gradual distancing from the child - Bedtime fading - Positive reinforcement - Bedtime Pass - Social story Sensory experiences that affect children's sleep: - Hearing (e.g., music, white noise, etc.) - Vision (mind jar, coloring mandala, puzzles etc.) - Touch (e.g., Wilbarger protocol, Qigong Massage, etc.) - Searching for oral motor sensation and fidgets (oral fidget, Chewing special foods such as carrot and celery) - Internal sensations, temperature and itching - Vestibular (e.g., air walker swing, rocking chair, etc.) - Sensory nest Yoga exercises for children's sleep Regulating excitement to improve children's sleep: - Redefining the situation from the third person's point of view. - Art and music
Environment-related factors	Points related to the child's sleeping environment What about my other children?
Impact of other activities on sleep	What activities affect my child's sleep? The role of nutrition in sleep

Table 2. Changes in sleep problems and hours

Participant	Children's Sleep Habits Questionnaire (Sleep problems)		Sleep Diary (Average hours of sleep)	
	Baseline	After intervention	Baseline	After intervention
# 1	45	42	7.02	7.07
# 2	47	45	9.2	9.57
# 3	48	45	7.2	7.57

summarized version of the massage steps was provided in the form of schematic illustrations, allowing parents to recall each step more quickly and clearly during the massage.

Simultaneously, caregiver feedback, quantitative data from the MPOC-20 questionnaire, and adherence rates were reviewed to triangulate and prioritize the findings. Based on this integrated analysis, specific revisions were made to the booklet. This iterative process ensured that the final version of the booklet was directly informed by user experiences, thereby enhancing its acceptability and feasibility.

In summary, this phase of the study assessed an initial implementation of the intervention. Although the observed 2–3 point changes in CSHQ scores fall below the conventional threshold for clinical significance reported in prior studies, they nevertheless indicate that more substantial improvements may be attainable in future research utilizing clinical trial designs, provided that necessary refinements are made to the implementation procedures of the intervention. Qualitatively, parents perceived the intervention as acceptable and feasible; however, several practical challenges related to child engagement and resource constraints were identified. Collectively, these results pave the way for a more in-depth discussion regarding the intervention's real-world applicability and its potential mechanisms of effect.

Discussion

This study outlines the development process of an occupational therapist-guided, parent-mediated intervention designed to improve sleep in children with ASD. It is important to note that this study primarily focused on development and feasibility rather than demonstrating the intervention's effectiveness. The family-centered paradigm and general systems theory provided the conceptual foundations for this study, offering a comprehensive framework for the program and highlighting the interactions within the family system. Consequently, self-regulation theories were directly applied to the development of intervention strategies, and the decisions made regarding the intervention were guided by principles consistent with self-regulation theory.

The initial version of the guide was developed based on a comprehensive literature review and refined through input from a panel of experts and caregivers to establish both content and face validity. The final version was produced following revisions informed by findings from a pilot study. Unlike existing interventions that focus solely on behavioral strategies (e.g., sleep hygiene; (47)) or sensory strategies (e.g., massage; (48)), this booklet integrates child, environmental, and sleep factors, offering a novel system-oriented approach to comprehensively address

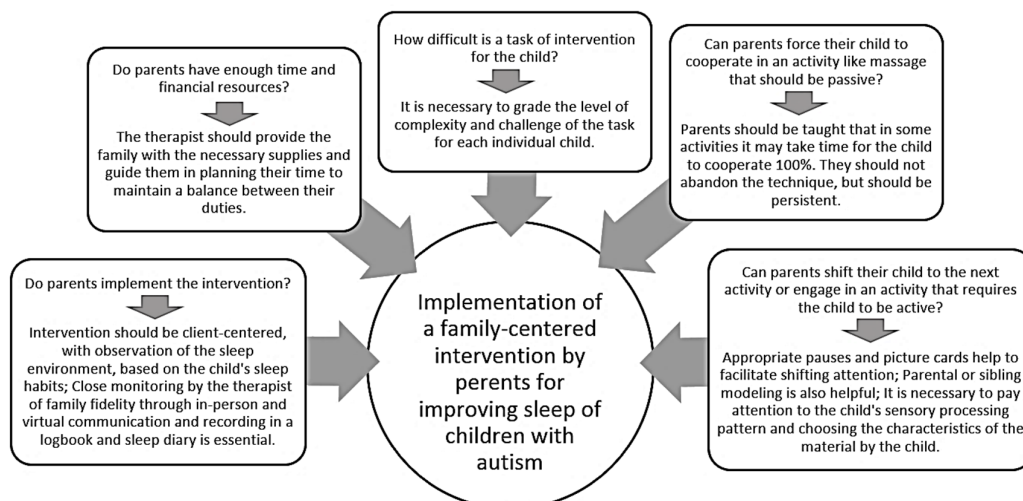


Figure 2. Factors affecting the implementation of parent guide for improving sleep in children with autism spectrum disorder

sleep disturbances in individuals with ASD. Key considerations for designing such an intervention are summarized in Figure 2.

The pilot study supported the hypothesis that occupational therapist supervision is essential for the effective parental implementation of sensory strategies. Without expert guidance, parents may misinterpret a child's sensory thresholds; for example, they might confuse sensory-seeking behaviors with avoidance, which can lead to ineffective or even counterproductive interventions. Occupational therapists play a crucial role in assisting families to correctly apply the strategies outlined in the booklet, tailoring them to the child's unique sensory profile as conceptualized by Dunn's sensory processing model (45).

Although the aim was not to assess effectiveness and thus a p-value was not calculated, a comparison of CSHQ scores indicated a small decrease. This decrease in the CSHQ score (2-3 points) aligns with changes observed in sensory interventions (2-5 points) (26), but is smaller than the change resulting from behavioral interventions (average 7 points, large effect size (1.24)) (49) in previous studies, highlighting the need for greater emphasis on behavioral strategies in sleep interventions. The modest changes in CSHQ scores can be attributed to two primary factors. First, intervention materials were not provided to families at the outset; delays in acquiring the necessary supplies reduced the effective duration of the two-month intervention. This finding aligns with Dawson-Squibb (2020), who emphasized that family-centered interventions require all necessary equipment to be provided in a packaged format at the beginning (50). Second, in accordance with Scahill (2016) (51, 52), more intensive monitoring of parental adherence—ideally over 10 or more sessions instead of 4-5—may have been necessary. Although parents had agreed via informed consent to implement the interventions and document them in the logbook and sleep diary, many failed to record consistently, raising concerns about adherence. While future implementations will aim to improve parental adherence through digital reminders and peer support

groups, the more fundamental constraints of time and limited resources, identified in this pilot, must first be addressed (50).

Massage was incorporated as a core component of the intervention in the present study (5). However, initial non-cooperation observed in some participants suggests that the therapeutic effects of massage can only be reliably evaluated once the child has fully acclimated to and accepted the procedure. This finding is consistent with the work of Rodrigues (2019), who similarly emphasized that children with ASD often require a significant acclimatization period to tolerate all stages of therapeutic massage (53).

In our study, the MPOC-20 played a crucial role in enhancing service delivery based on parent feedback. For example, the duration of face-to-face sessions with each parent was extended to facilitate a more thorough exploration of the factors influencing the child's sleep, allowing for necessary adjustments to be made. Parents reported feeling empowered by the opportunity to implement sleep interventions at home. They expressed satisfaction with the provision of written instructions in a booklet format, which enabled them to access and review the information multiple times.

Limitations

The booklet was developed in accordance with the four-phase framework outlined in the updated Medical Research Council (MRC) guidance for complex interventions (54). Throughout these phases, we considered core elements such as the effects of context, stakeholder engagement, identification of key uncertainties, and refinement of the intervention. However, economic considerations were not included as part of the core elements of this framework. Although the booklet features several interventions that require costly equipment—which may impose a financial burden on some families—the research team opted not to exclude any interventions to maintain the general applicability of the guide. We did not develop a program theory based on the MRC framework because existing theories,

specifically family-centered and general systems theories, sufficiently justified the intervention by emphasizing caregiver empowerment and the dynamic interactions between child sleep and the environment, as validated through expert and parent feedback (19, 55).

This pilot study was designed to be formative; its primary objectives were to refine the intervention protocol and assess its feasibility and acceptability. Due to the small and homogeneous sample, the absence of a control group, and the lack of long-term follow-up, the results are not indicative of efficacy and cannot be generalized. Therefore, the findings should be interpreted as preliminary. Additionally, the results may be subject to bias due to the therapist's involvement in both training and fidelity assessment.

A full-scale clinical trial with an adequate sample size is necessary to rigorously evaluate the intervention's efficacy and establish its clinical significance. The next phase of this research program will focus on conducting this confirmatory trial.

Conclusion

The design of the sleep guide for parents of autistic children was informed by the understanding that the dynamic interplay among the child, the environment, and sleep itself must be considered as an integrated whole. Given the challenges that children with ASD face in self-regulation, environmental factors—such as diet and screen time—can disproportionately disrupt their sleep compared to typically developing children. A singular focus on any one dimension constitutes a reductionist approach, as noted in prior literature. In contrast, by adopting a holistic perspective on self-regulation, this intervention aims to address sleep disturbances and may also alleviate core autism symptoms, repetitive behaviors, and sensory reactivity through the optimization of CNS arousal (2). The 'Parent Guide' translates this holistic theory into a concrete, actionable, and manualized tool for clinical practice. Its unique value lies in its dual focus: it simultaneously addresses the multifaceted biological and behavioral underpinnings of sleep problems in ASD while being designed for real-world implementation by families at home. This positions the guide as a novel solution that bridges the gap between complex theoretical models and the practical needs of both clinicians and families.

Building on these promising pilot data, we plan to conduct a randomized controlled trial (RCT) with a larger sample size and follow-up assessments. To facilitate scalable and sustainable implementation, we propose disseminating the booklet through occupational therapy clinics, supplemented by online delivery, instructional videos, and downloadable resources. Additionally, we will train therapists to assist parents in customizing strategies to meet individual needs.

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Conflict of Interests

The authors declare that they have no competing interests.

Authors' Contributions

All authors contributed to the conception and design of the study. They participated in preparing the booklet and implementing the intervention. S.K.E. and S.A. collected the data, while J.A. interpreted the data. M.A. and S.A. prepared the tables and drafted the manuscript. S.K.E. created the figure and revised the manuscript. All authors read and approved the final version of the manuscript.

Ethical Considerations

Written informed consent was obtained from all participating parents. Verbal consent was also sought from the children, provided they had adequate communication skills and comprehension. The study protocol complied with the ethical guidelines of the 1975 Declaration of Helsinki and received approval from the ethics committee of Iran University of Medical Sciences (Code: IR.IUMS.REC.1402.805).

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Data Availability

Data of this study is available from the corresponding author upon reasonable request.

AI Use Statement

Artificial Intelligence was used for editing the final text.

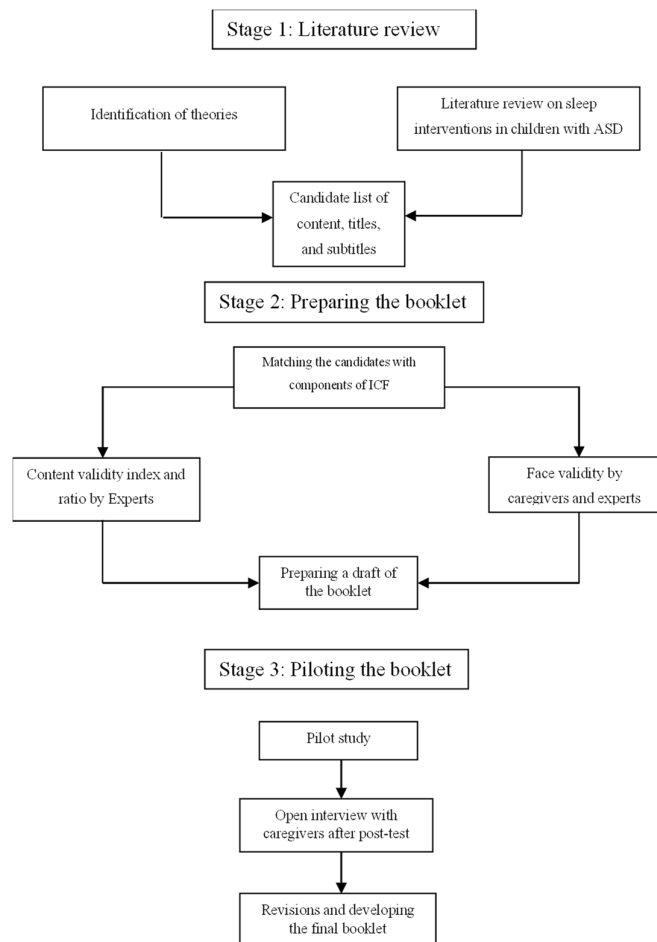
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Appendix 1. Information to include when describing an intervention and the location of the information (Based on main document file)

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
1.	BRIEF NAME Provide the name or a phrase that describes the intervention.	Page 1	_____
2.	WHY Describe any rationale, theory, or goal of the elements essential to the intervention.	Pages 3,4,6, and 7 of this manuscript	_____
3.	WHAT Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	Page 11 (In the intervention section of this manuscript)	It is also specified in various sections of the sleep guide.
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	Page 11 (In the intervention section of this manuscript)	It is also specified in various sections of the sleep guide.
5.	WHO PROVIDED For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	Page 16, (in the first line of Discussion in this manuscript)	It is also specified in various sections of the sleep guide.
6.	HOW Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	Page 11 of this manuscript, modes of delivery were described in the first two lines of second paragraph in the intervention section – the last line of the second paragraph of the intervention section of this manuscript described how it was provided individually.	It is also specified in various sections of the sleep guide.
7.	WHERE Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	Page 11 (The Intervention section of manuscript describe where the intervention occurs and any necessary infrastructure or relevant features.)	It is also specified in various sections of the sleep guide.
8.	WHEN and HOW MUCH Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	Page 11 (first two lines of second paragraph in the intervention section) of this manuscript	It is also specified in various sections of the sleep guide.
9.	TAILORING If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	Pages 10 to 12 (Measures and Intervention sections of manuscript) fully explained.	It is also specified in various sections of the sleep guide.
10.†	MODIFICATIONS If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	Pages 8 of the manuscript (Content validity and face validity / last paragraph of page 9 of the manuscript (prior to the measures) / supplementary file 6	_____
11.	HOW WELL Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	last paragraph of Page 11 in the manuscript	_____
12.†	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	First paragraph of page 12 in the manuscript	_____



Appendix 2. Stages of the booklet development process

Appendix 4. Sensory strategies recommended for participants based on sensory processing patterns

Participant	Children sensory processing patterns	Content of the booklet (Sensory strategies)
# 1	Sensitivity in hearing low registration in touch	White noise machine / Calming music Tactile fidgets / Sensory Box / Qigong Massage with firmer strokes
# 2	Seeking in vision Sensitivity in touch	Mind jar / Coloring mandala / Completing color puzzles Qigong Massage with slow transition on the different parts of body and deep pressure
# 3	Sensitivity in vestibular	Rocking chair with slow and rhythmic motions.

Appendix 5. Summary of studies reviewed in the literature review

Author (Year)	Participants	aims	Study design	control or comparison group	Findings	
Behavioral Interventions						
1	Tan-MacNeill et al., 2020 (1)	20 parents or caregivers of children with pervasive developmental disorders aged 4 to 10	assessing the feasibility and acceptability of BNBD interventions (including routine bedtime training, independent sleeping, sleep scheduling, etc.) from the perspective of parents over five educational sessions	Feasibility	No	Participants reported that the intervention was usable, useful, acceptable, and feasible.
2	Jin CS et al., 2013 (2)	Three young children, 2 of whom had been diagnosed with autism	assessing the effects of assessment-based behavioral interventions on the treatment of sleep problems in children	Single-subject	No	Decreases in sleep-onset delay and sleep interfering behaviors were evident for all three children.
3	Stuttard et al., 2015(3)	Twenty-three parents of children aged 5–15 with intellectual disabilities	Reporting the findings from the initial assessment of 'Managing Your Child's Behavior to Improve Sleep,' presented in a group setting	preliminary	No	The improvements observed in children's nocturnal awakenings were statistically significant, and an enhanced sense of parental efficacy was evident. Also, the intervention was both cost-effective and acceptable.
4	McLay et al., 2019 (4)	two children with ASD	Evaluating the effectiveness of Functional Behavioral Assessment-based interventions for sleep disorders in children with ASD	case study	No	The results of the study indicated a reduction in sleep disturbances for each participant, although sleep-onset delay persisted for one participant. These outcomes were maintained at both short-term and long-term follow-up
5	Malow et al., 2014 (5)	80 children aged 2 to 10 years with ASD and sleep problems, along with their parents	To determine whether the individual format of the 'Autism Treatment Network Sleep Interventions' is more effective than the group format in improving sleep, daily behavior, and family functioning	Randomized Control Trial	Yes	parent-based sleep education, delivered in a limited number of sessions, was associated with improvements in sleep-onset delay in children with ASD. Group versus individual training had no effect on the outcomes.
6	Reed et al., 2009 (6)	20 families of children aged 3–10 years with ASD	Examining the effect of a three-session, two-hour each, sleep behavior training workshop for parents on insomnia in children with ASD	Pilot study	No	Brief parent-based workshops on behavioral sleep training were effective in improving both subjective and objective sleep measures, sleep habits, and daytime behavior in children.

Appendix 5. Continued

Author (Year)	Participants	aims	Study design	control or comparison group	Findings	
Behavioral Interventions						
7	Moon et al., 2010 (7)	Three children aged 5 to 9 years with ASD	Evaluating the effectiveness of a multi-component, manualized behavioral sleep intervention for children with ASD and insomnia.	Single-subject	No	In all three children, the average sleep-onset delay decreased following the intervention, and these improvements were generally maintained at the 12-week follow-up.
8	Johnson et al., 2013 (8)	Parents of 40 children aged 2 to 6 years with ASD	Developing a manualized behavioral parent training (BPT) program for parents of young children with ASD and sleep disturbances	pilot trial	Yes	The BPT program group demonstrated significant improvements compared to the comparison group for the primary sleep outcome
9	San berg et al., 2018 (9)	Three children aged 4 to 8 years with ASD	Evaluating the effectiveness of bedtime fading in reducing sleep disturbances in children with ASD, implemented by parents in the home environment.	Single-subject	No	The results indicated that the intervention was effective in eliminating co-sleeping, reducing frequent night awakenings, and decreasing sleep-onset dependency. Secondary improvements included a reduction in sleep-onset latency. Follow-up data showed that these gains were maintained, and parents also reported high levels of satisfaction.
10	Hunter et al., 2021 (10)	Three children aged 3 to 6 years with ASD	Examining the Effectiveness of Performance-Based Behavioral Interventions on Sleep Problems and Interfering Stereotyped Behaviors in Children with ASD	Single-subject	No	Sleep problems decreased in two children, and the duration of stereotyped behaviors was reduced across all participants. The treatment effects were largely maintained during the follow-up period, and parent-reported satisfaction was high.
11	Van Deurs et al., 2021 (11)	Eight children aged 9 to 15 years with ASD	Effectiveness and Maintenance of Cognitive-Behavioral Therapy in Children with ASD	Case study	No	The treatment was effective in reducing sleep disturbances (e.g., night awakenings, unwanted co-sleeping) for all participants, and the results were largely maintained during the follow-up period.
12	McLay et al., 2019 (12)	Seven children aged 4 to 5 years with ASD	Examining the Effectiveness of functional behavioral assessment (FBA) - Based Interventions (reinforcement, social story) on Sleep Problems, Particularly Co-Sleeping, in Children with ASD	Single-subject	No	Improvements were observed across all sleep problems, including the elimination of co-sleeping. Positive effects were maintained at follow-up for five of seven children, although two participants did not complete the intervention.
13	Christodulu et al., 2004 (13)	Four children aged 2 to 6 years with developmental disorders	Examining Behavioral Interventions Designed to Reduce Sleep Problems in Young Children with Developmental Disorders	Single-subject	No	The study's findings supported the consideration of consistent sleep schedules (maintaining fixed bedtimes and wake times), along with a bedtime routine, for treating sleep disturbances in children with developmental disabilities. Additionally, parents in this study found the interventions was easy and practical to implement.
14	Weiskop et al., 2005 (14)	Thirteen children with autism, Asperger's syndrome, or Fragile X syndrome, aged between 3 and 8 years	Evaluating a Parent Training Program Using Behavioral Principles to Reduce Children's Sleep Problems	Single-subject	No	Difficulties with settling, night awakenings, and co-sleeping were reduced. The program demonstrated high social validity, and the outcomes were clinically meaningful and maintained at follow-up
15	Wiggs and Stores, 2001 (15)	Thirty children aged 6 to 13 years with intellectual disabilities	Assessing the Psychological Status of Mothers and Fathers Following Behavioral Intervention for Sleep Problems	Randomized Control Trial	Yes	The findings demonstrated that the behavioral intervention effectively improved sleep problems and daytime behavioral issues in children with severe intellectual disabilities and had a positive impact on mothers, and to a lesser extent, on fathers.
16	Knight et al., 2014 (16)	Three children aged 4 to 5 years with ASD	Examining the Effectiveness of a Behavioral Treatment Package (White Noise, Graduated Extinction, Bedtime Routine) for Sleep Problems in Children	Single-subject	No	The results indicated that the treatment package was effective in reducing sleep onset delay and the frequency of night awakenings. One-week follow-up data showed continued improvement.
17	Moore P., 2004 (17)	4-year-old boy with ASD and severe learning disabilities	describing the use of a social story as part of a behavioral intervention on the sleep behaviors.	Case study	No	Results show that a social story effectively reduces sleep problem in a child with ASD and developmental disability.
18	Didden et al., 2004 (18)	Three children aged 9 to 12 with developmental disabilities	Evaluating the Effectiveness of Behavioral Therapy in Reducing Sleep Problems	Single-subject	No	Behavioral treatment was effective in reducing sleep problems and nighttime disruptive behaviors in children, and the treatment effects were maintained during the follow-up period.
19	Israelsen, 2020 (19)	19 children aged 4 to 10 with ASD.	Examining the feasibility, acceptability and effect of using a social story on bedtime routine as a complementary intervention	Feasibility study	No	Results from this study indicated social stories are acceptable as a complementary tool to sleep treatment.
20	Woodford et al., 2023 (20)	Nine autistic children and children with Rare Genetic Neurodevelopmental Disorders aged 4 to 12	Investigating the effectiveness and acceptability of less restrictive behavioral interventions (i.e., specifically excluding extinction) for sleep problem	A Single Case Feasibility Study	No	Results demonstrated a reduction in sleep disturbance including unwanted bed-sharing, night waking and sleep onset delay for 3/3, 5/5 and 6/7 children respectively, which were maintained at follow-up.

Appendix 5. Continued

Author (Year)	Participants	aims	Study design	control or comparison group	Findings	
Sensory Interventions						
21	Akarsu et al., 2021 (21)	A 12-year-old boy with autism	Examining the effects of sensory integration therapy and a foot reflexology application on sensory modulation and sleep	Single-subject	No	Sensory integration therapy combined with a foot reflexology program may have positive effects on sensory modulation and sleep habits in a boy with autism who experiences sleep difficulties
22	Fazlıođlu Y, Baran G , 2008 (22)	30 children between 7 and 11 years of age with autism	investigating the effect of a sensory integration therapy program on sensory problems of children with autism	Semi-experimental	Yes	Statistically significant differences in the sensory characteristics between groups indicated that the sensory integration therapy program positively affected sensory processing and sleep problems treated children.
23	Silva et al., 2007 (23)	13 children with autism between the ages of 3 and 6	investigating whether the responses described after massage therapy in the case series could be duplicated in a small controlled study with blinded examiners	Replicability	Yes	The study results showed an overall improvement in sensory processing scores on the sensory profile after massage and parents reported improvements in falling asleep at a consistent time, falling asleep more quickly, and sleeping through the night.
24	Mindell et al., 2018 (24)	123 mothers and their 3- to 18-month-old infant	examine the impact of a massage-based bedtime routine on infant sleep, maternal sleep, and maternal mood	Randomized Control Trial	Yes	This bedtime routine resulted in improvements in child and mother night wakings, maternal perceptions of child sleep and mood (ie, sleep problem, bedtime ease, and morning mood), and improvements in maternal sleep quality
25	Silva et al., 2009 (25)	46 children with ASD aged 3–6 years	Examining the effect of 5 months of Qigong Sensory Treatment (QST) on improving sensory impairments, digestion, and sleep	Randomized Control Trial	Yes	Treated children showed significant gains in social and language skills, reduced autistic behaviors, and improved sleep. These findings support a model for understanding and treating sensory and self-regulation difficulties in autism.
26	Silva et al., 2011 (26)	47 children with ASD aged 3–6 years	Examining the effects of a parent-delivered qigong massage program	Randomized Control Trial	Yes	Treated children showed significant gains in autism-related behavior, social and language skills, and sensory/self-regulation, with parents reporting better sleep and fewer night awakenings.
27	Silva et al., 2013 (27)	129 children with autism aged 3–6 years	Evaluating if Qigong massage reduces tactile abnormalities and improves self-regulation	Retrospective study	Yes	The results show that Qigong massage can improve emotional and behavioral self-regulation in preschool aged children, as well as difficulties with earlier self-regulation milestones relative to sleep, digestion, self-soothing, and attention.
28	Silva et al., 2015 (28)	103 preschool children with autism	evaluate initial 5-month massage on severity of autism and on sensory abnormalities and self-regulatory delay	Replication study	Yes	The QST program led to a reduction in the intensity of sensory, behavioral, and language components in individuals with autism. In addition, parents reported improvement in their child's sleep.

Appendix 5. Continued

Author (Year)	Participants	aims	Study design	control or comparison group	Findings	
Sensory Interventions						
29	Hamza et al., 2023 (29)	60 children post abdominal surgeries aged 3–8 years	To determine the effect of massage therapy on sleep disturbances and pain control for children post abdominal surgeries	quasi-experimental	Yes	The results showed children in the study group significantly improved of sleep disturbances and physiological measurement decreased pain level after implementing massage therapy postoperatively.
30	Escalona et al., 2001 (30)	Twenty children with autism aged 3–6 years	Examining and comparing the effects of 15-minute pre-sleep massage versus story reading on sleep problems, hyperactivity, and stereotyped behaviors	Randomized Control Trial	Yes	Children in the massage group showed fewer stereotyped behaviors, more task-focused and socially engaged behaviors during school play observations, and fewer sleep problems at home.
31	Cullen et al., 2005 (31)	Nine children with autism aged 2–13 years	Exploring the experience of touch before, during, and after a parent-delivered training and support program (e.g., massage) in the parents and children with ASD	Exploratory study	No	Touch therapy led to relaxation and sleepiness in 5 of 7 children, and improved sleep patterns in 6 of 7 children who had reported sleep problems. Another benefit of the intervention was increased parent-child closeness.
32	Liu et al., 2023 (32)	Fifty-two preschool children with ASD	Examining the effects of the Parent-Child Sand play Therapy (PCST) program on autistic behaviors, social responsiveness, and sleep quality in preschool children with ASD, as well as maternal stress	Randomized Control Trial	Yes	The PCST program improved social interaction and sleep quality in preschool children with ASD, while also reducing parental stress.
Yoga						
33	Tanksale et al., 2021 (33)	Sixty-seven children with ASD aged 8–12 years	Examining the effects of a yoga-based program combined with cognitive-behavioral therapy on self-regulation	Pilot Randomized Control Trial	Yes	Participants in the intervention group showed significant improvements in overall executive control both post-program and at follow-up compared to the control group. Parents also reported reductions in certain sleep problems after the intervention.
34	Courvill et al., 2023 (34)	10 children with ASD aged 7–12 years	Examining the effects of a yoga program on the quality of sleep of children	Single-subject	No	Results show that after yoga program, children were less resistant in going to sleep.
Emotion regulation						
35	Liu C, 2017 (35)	41 school-aged children with traumatic experiences	Examining the efficacy of a Solution-Focused Art Therapy (SF-AT) intervention on treating PTSD and sleep symptoms	Pilot Randomized Control Trial	Yes	The study has shown SF-AT is beneficial as a complementary treatment for PTSD symptoms and sleep issues in children with traumatic experience and corresponding symptoms.

Appendix 5. Continued

Guidelines	
1	<p>New Zealand Autism Spectrum Disorder Guideline</p> <p>Citation: Ministries of Health and Education. 2016. New Zealand Autism Spectrum Disorder Guideline (2nd edn). Wellington: Ministry of Health. First published in March 2008, 2nd edition July 2016 by the Ministry of Health PO Box 6140, Wellington, New Zealand ISBN: 978-0-947515-00-3 (print) ISBN: 978-0-947515-01-0 (online) HP 6395 This document is available on the Ministry of Health's website: health.govt.nz)</p>
2	<p>Practice guideline: Treatment for insomnia and disrupted sleep behavior in children and adolescents with autism spectrum disorder</p> <p>Ashura Williams Buckley, MD, Deborah Hirtz, MD, Maryam Oskoui, MD, Melissa J. Armstrong, MD, MSc, Anshu Batra, MD, Carolyn Bridgemohan, MD, Daniel Coury, MD, Geraldine Dawson, PhD, Diane Donley, MD, Robert L. Findling, MD, MBA, Thomas Gaughan, David Gloss, MD, MPH&TM, Gary Gronseth, MD, Riley Kessler, Shannon Merillat, MLIS, David Michelson, MD, Judith Owens, MD, MPH, Tamara Pringsheim, MD, Linmarie Sikich, MD, MA, Aubyn Stahmer, PhD, Audrey Thurm, PhD, Roberto Tuchman, MD, Zachary Warren, PhD, Amy Wetherby, PhD, Max Wiznitzer, MD, and Stephen Ashwal, MD Neurology® 2020;94:392-404. doi:10.1212/WNL.0000000000009033</p>
3	<p>Occupational Therapy Practice Guidelines for Individuals with Autism Spectrum Disorder</p> <p>2016 by the American Occupational Therapy Association, Inc. All rights reserved. ISBN-13: 978-1-56900-462-3 (ebook)</p>

Appendix 6. The opinions of families and experts for preparing the booklet

Experts' feedback	Changes to the booklet	Parents' feedback
Specialized English words should be removed from the text and replaced with footnotes to make it understandable for the family.	The necessary corrections were made to the text and the text was edited.	Some of the terms identified require footnotes. The specified parts of the booklet should be written in a simpler way.
Add a bedtime pass image to the booklet.	The bedtime pass image was added to the booklet.	----
Phrases such as "Research shows that..." should be removed from the text.	Phrases such as "research shows that..." were removed from the text.	----
It is best to change the child's position in the air walker swing from prone to supine.	The child's position in image of air walker swing was corrected from prone to supine.	----
Indicate in the booklet that "Use of the booklet by the child's primary caregiver requires therapist training."	We mentioned in the booklet that the strategies should be done with the guidance of a therapist.	----
Due to the large amount of content in the booklet, families may not have the opportunity to read the entire booklet. A summary of the contents should be provided to the family.	In order to summarize the content of the booklet, the necessary content for the family were identified from the booklet's list.	----
Mandala images are complex and difficult for children.	Mandala images were replaced with simple designs.	Mandala images are complex and difficult for children.