Insomnia in adult patients with cancer: ESMO Clinical Practice Guideline

SUPPLEMENTARY MATERIAL

Supplementary Table S1. Classification of sleep–wake disorders and criteria for insomnia disorder in the ICD-11, DSM-5-TR and ICSD[1-3]

ICD-11	DSM-5-TR	ICSD third edition
Sleep–wake disorders are characterised by difficulty initiating or maintaining sleep (insomnia disorders), excessive sleepiness (hypersomnolence disorders), respiratory disturbance during sleep (sleep-related breathing disorders), disorders of the sleep–wake schedule (circadian rhythm sleep–wake disorders), abnormal movements during sleep (sleep-related movement disorders) or problematic behavioural or physiological events that occur while falling asleep, during sleep or upon arousal from sleep (parasomnia disorders) **Insomnia disorder** Characterised by the complaint of persistent difficulty with sleep initiation,	Sleep–wake disorders encompass 10 disorders or disorder groups: insomnia disorder, hypersomnolence disorder, narcolepsy, breathing-related sleep disorders, circadian rhythm sleep–wake disorders, non-REM sleep arousal disorders, nightmare disorder, REM sleep behaviour disorder, restless legs syndrome and substance or medication-induced sleep disorder **Insomnia disorder** A: A predominant complaint of dissatisfaction with sleep quantity or quality associated with one (or more) of the following symptoms:	Identifies six major categories, namely insomnia disorders, sleep-related breathing disorders, central disorders of hypersomnolence, circadian rhythm sleep–wake disorders, sleep-related movement disorders and parasomnias, as well as a seventh category for other sleep disorders **Insomnia** A persistent difficulty with sleep initiation, duration, consolidation or quality that occurs despite adequate opportunity and circumstances for sleep, and results in some form of daytime impairment • The patient reports, or the patient's parent or caregiver observes, one or

duration, consolidation or quality that occurs despite adequate opportunity and circumstances for sleep, and results in some form of daytime impairment. Daytime symptoms typically include fatigue, depressed mood or irritability, general malaise and cognitive impairment. Individuals who report sleep-related symptoms in the absence of daytime impairment are not regarded as having an insomnia disorder. Specify if: • Chronic: sleep disturbance and associated daytime symptoms occur at least several times per week for ≥3 months. Some individuals with chronic insomnia may show a more episodic course, with recurrent episodes of sleep–wake difficulties lasting several weeks at a time over several years. If the insomnia is due to another sleep–wake disorder, a	• Difficulty initiating sleep (in children, this may manifest as difficulty initiating sleep without caregiver intervention) • Difficulty maintaining sleep, characterised by frequent awakenings or problems returning to sleep after awakenings (in children, this may manifest as difficulty returning to sleep without caregiver intervention) • Early morning awakening with inability to return to sleep B: The sleep disturbance causes clinically significant distress or impairment in social, occupational, educational, academic, behavioural or other important areas of functioning C: The sleep difficulty occurs ≥3 nights per week	more of the following: (i) difficulty initiating sleep, (ii) difficulty maintaining sleep, (iii) waking up earlier than desired, (iv) resistance to going to bed on appropriate schedule, (v) difficulty sleeping without parent or caregiver intervention • The patient reports, or the patient's parent or caregiver observes, one or more of the following related to the night-time sleep difficulty: (i) fatigue or malaise, (ii) attention, concentration or memory impairment, (iii) impaired social, family, vocational or academic performance, (iv) mood disturbance or irritability, (v) daytime sleepiness, (vi) behavioural problems (e.g. hyperactivity, impulsivity, aggression), (vii) reduced motivation, energy or initiative, (viii) proneness for errors or

mental disorder, another medical condition or a substance or medication, chronic insomnia should only be diagnosed if the insomnia is an independent focus of clinical attention • Short term: difficulty initiating or maintaining sleep lasting <3 months. If the insomnia is due to another sleep–wake disorder, a mental disorder, another medical condition or a substance or medication, short-term insomnia should only be diagnosed if the insomnia is an independent focus of clinical attention **Hypersomnolence disorder** Narcolepsy; idiopathic hypersomnia; Kleine-Levin syndrome; hypersomnia due to a medical condition; hypersomnia due to a medication or substance;	D: The sleep difficulty is present for ≥3 months E: The sleep difficulty occurs despite adequate opportunity for sleep F: The insomnia is not better explained by and does not occur exclusively during the course of another sleep–wake disorder (e.g. narcolepsy, a breathing-related sleep disorder, a circadian rhythm sleep–wake disorder, a parasomnia) G: The insomnia is not attributable to the physiological effects of a substance (e.g. a drug of abuse, a medication) H: Coexisting mental disorders and medical conditions do not adequately explain the predominant complaint of insomnia Specify if:	accidents, (ix) concerns about or dissatisfaction with sleep • The reported sleep–wake complaints cannot be explained purely by inadequate opportunity (i.e. enough time is allotted for sleep) or inadequate circumstances (i.e. the environment is safe, dark, quiet and comfortable) for sleep • The sleep–wake difficulty is not better explained by another sleep disorder Specifiers: • Chronic: the sleep disturbance and associated daytime symptoms occur at least three times per week and have been present for ≥3 months • Short term: the sleep disturbance and associated daytime symptoms have been present for <3 months

hypersomnia associated with a mental disorder; insufficient sleep syndrome **Sleep-related breathing disorders** Central sleep apnoeas; obstructive sleep apnoea; sleep-related hypoventilation or hypoxaemia disorders; unspecified **Circadian rhythm sleep–wake disorders** Delayed sleep phase syndrome; advanced sleep–wake phase disorder; irregular sleep–wake pattern; non-24-hour sleep–wake rhythm disorder; circadian rhythm sleep–wake disorder, shift work type; circadian rhythm sleep–wake disorder, jet lag type; unspecified **Sleep-related movement disorders** Restless legs syndrome; periodic limb movement disorder; sleep-related leg cramps; sleep-related bruxism; sleep-related rhythmic movement disorder;	• With mental disorder, including substance use disorders • With medical condition • With another sleep disorder Specify if: • Episodic: symptoms last ≥1 month but <3 months • Persistent: symptoms last ≥3 months • Recurrent: two (or more) episodes within the space of 1 year **Hypersomnolence disorder** With mental disorder, including substance use disorders; with medical condition; with another sleep disorder; acute, subacute, persistent **Narcolepsy** With cataplexy or hypocretin deficiency (type 1); without cataplexy and either without hypocretin deficiency or	**Sleep-related breathing disorders** Obstructive sleep apnoea disorders; central sleep apnoea syndromes; sleep-related hypoventilation disorders; sleep-related hypoxaemia disorder; isolated symptoms and normal variants **Central disorders of hypersomnolence** Narcolepsy type 1; narcolepsy type 2; idiopathic hypersomnia; Kleine-Levin syndrome; hypersomnia due to a medical disorder; hypersomnia due to a medication or substance; hypersomnia associated with a psychiatric disorder; insufficient sleep syndrome **Circadian rhythm sleep–wake disorders** Delayed sleep–wake phase disorder; advanced sleep–wake phase disorder; irregular sleep–wake rhythm disorder; non-24-hour sleep–wake rhythm disorder; shift work disorder; jet lag

benign sleep myoclonus of infancy; propriospinal myoclonus at sleep onset; sleep-related movement disorder due to a medical condition; sleep-related movement disorder due to a medication or substance **Parasomnia disorders** Disorders of arousal from non-REM sleep; parasomnias related to REM sleep; other parasomnias	hypocretin unmeasured (type 2); cataplexy or hypocretin deficiency due to a medical condition; without cataplexy and without hypocretin deficiency due to a medical condition **Obstructive sleep apnoea hypopnoea** **Central sleep apnoea** Idiopathic central sleep apnoea; Cheyne-Stokes breathing **Sleep-related hypoventilation** Idiopathic hypoventilation; congenital central alveolar hypoventilation; comorbid sleep-related hypoventilation **Circadian rhythm sleep–wake disorders** Delayed sleep phase type; advanced sleep phase type; irregular sleep–wake type; non-24-hour sleep–wake type; shift work type; unspecified **Parasomnias**	disorder; circadian sleep–wake disorder not otherwise specified **Parasomnias** Non-REM-related parasomnias; REM-related parasomnias; other parasomias **Sleep-related movement disorders** Restless legs syndrome; periodic limb movement disorder; sleep-related leg cramps; sleep-related bruxism; sleep-related rhythmic movement disorder; benign sleep myoclonus of infancy; propriospinal myoclonus at sleep onset; sleep-related movement disorder due to a medical disorder; sleep-related movement disorder due to a medication or substance; sleep-related movement disorder, unspecified **Other sleep disorder**

	Non-REM sleep arousal disorders **Nightmare disorder** **REM sleep behaviour disorder** **Restless legs syndrome and substance- or medication-induced sleep disorder**	

DSM-5-TR, American Psychiatric Association Diagnostic and Statistical Manual of Mental Disorders fifth edition – Text Revision; ICD-11, World Health Organization International Classification of Diseases 11th edition; ICSD, International Classification of Sleep Disorders; REM, rapid eye movement.

Supplementary Table S2. The 3-P model of insomnia in patients with cancer[4]

Predisposing factors	Precipitating factors	Perpetuating factors
Female sex Anxiety-prone personality Family or personal history of insomnia and/or anxiety or depression Endocrine modifications of circadian rhythms and irregular exposure to light Current psychiatric disorder (e.g. depression, anxiety)	Anxiety or distress related to cancer diagnosis and progression (e.g. death anxiety) Treatment-related factors: • Radiation therapy or hormone therapy with side effects or conditions that result in disrupted circadian rhythms • ChT (nausea or vomiting, fatigue) • Other drugs (e.g. corticosteroids, opiates) Cancer-related factors: • Cancer with increased steroid production Cancer-related symptoms such as pain, fatigue, hot flashes and vasomotor symptoms, pruritus Comorbid medical conditions (e.g. chronic pain conditions, hyperthyroidism, COPD or chronic renal disease) Surgery or hospitalisation	Maladaptive behaviours and beliefs that patients use to cope with sleep difficulties (i.e. extended time in bed, taking frequent and long naps, following an irregular sleep schedule and being physically inactive) Worries about sleeplessness and daytime consequences of poor sleep may delay sleep onset and cause frequent, prolonged awakenings in patients with cancer Feedback loops between extended time in bed and insomnia, depression and fatigue Problems during the night (e.g. snoring, nocturnal micturition)

ChT, chemotherapy; COPD, chronic obstructive pulmonary disease.

Supplementary Table S3. List of reviews, meta-analyses and interventional studies on the management of insomnia in patients with cancer

Study type	Publications
Reviews and meta-analyses	Fang et al. 2019[5] Gao et al. 2022[6] Geiger-Brown et al. 2015[7] Howell et al. 2014[8] Johnson et al. 2016[9] Ma et al. 2021[10] Mishra et al. 2012[11] Rusch et al. 2019[12] Squires et al. 2022[13] Takemura et al. 2020[14] Xiang et al. 2021[15] Zachariae et al. 2016[16]
Psychological interventions	Barsevick et al. 2010[17] Barton et al. 2020[18] Berger et al. 2009[19] Casault et al. 2015[20] Dean et al. 2020[21] Epstein et al. 2007[22] Espie et al. 2008[23] Fiorentino et al. 2010[24] Garland et al. 2014[25] Lengacher et al. 2015[26] Matthews et al. 2014[27]

	Mercier et al. 2018[28] Padron et al. 2022[29] Palesh et al. 2018[30] Palesh et al. 2020[31] Ritterband et al. 2012[32] Roscoe et al. 2015[33] Savard et al. 2021[34] Savard et al. 2014[35] Savard et al. 2005[36] Zachariae et al. 2018[37] Zhang et al. 2017[38] Zhao et al. 2020[39]
Pharmacological interventions	Chen et al. 2014[40] Dimsdale et al. 2011[41] Hansen et al. 2014[42] Jacobsen et al. 1994[43] Jakobsen et al. 2022[44] Kurdi et al. 2016[45] Madsen et al. 2016[46] Palmer et al. 2020[47] Shahrokhi et al. 2021[48] Yennurajalingam et al. 2021[49]
Drug-drug interactions	Kalash et al. 1998[50] Pinucci et al. 2023[51] Riechelmann et al. 2007[52] Turossi-Amorim et al. 2022[53]

	Yap et al. 2011[54]
Other interventions	Chen et al. 2016[55] Fox et al. 2021[56] Nakamura et al. 2013[57] Nguyen et al. 2021[58] Roveda et al. 2017[59] Tang et al. 2010[60] Wu et al. 2021[61]

Supplementary Table S4. Typical doses of common pharmacological agents used in the treatment of insomnia in medical settings[62-65]

Drug	Dose, mg	Half-life, hours
Benzodiazepines[a]		
Triazolam[b,c]	0.125-0.25	1.5-5.5
Quazepam[b,c]	7.5-15	~39[d]
Flurazepam[b,c]	15-30	2.3[e]
Brotizolam[b]	0.125-0.25	3.6-7.9
Estazolam[b,c]	1-2	10-24
Temazepam[b,c]	15-30	10-15
Nonbenzodiazepines[f]		
Zolpidem[b,c]	10	2-3
Zopiclone[b,c]	7.5	3.5-6.5
Eszopiclone[b,c]	1-3	6
Orexin 1-orexin 2 receptor antagonists (DORAs)		
Daridorexant[b,c]	25-50	~8
Suvorexant[c]	10-20	8-19
Other		
Melatonin	2	

DORA, dual orexin receptor antagonist; EMA, European Medicines Agency; FDA, Food and Drug Administration.

[a]Benzodiazepines should be used for a short period of time (≤2 weeks) due to the risk of abuse, misuse, addiction, physical dependence and withdrawal reactions.

[b]Approved by the EMA for the treatment of disorders of sleep onset and/or sleep maintenance.

[c]Approved by the FDA for the treatment of disorders of sleep onset and/or sleep maintenance.

[d]Includes metabolites with a half-life of 79 hours.

[e]Includes metabolites with a half-life of 47-100 hours.

[f]Recommended for short-term use (≤2 weeks) due to the risk of abuse, misuse, addiction, physical dependence and withdrawal reactions.

Supplementary Table S5. Levels of evidence and grades of recommendation (adapted from the Infectious Diseases Society of America-United States Public Health Service Grading System[a])

Levels of evidence

I	Evidence from at least one large randomised, controlled trial of good methodological quality (low potential for bias) or meta-analyses of well-conducted randomised trials without heterogeneity
II	Small randomised trials or large randomised trials with a suspicion of bias (lower methodological quality) or meta-analyses of such trials or of trials demonstrated heterogeneity
III	Prospective cohort studies
IV	Retrospective cohort studies or case-control studies
V	Studies without control group, case reports, expert opinions

Grades of recommendation

A	Strong evidence for efficacy with a substantial clinical benefit, strongly recommended
B	Strong or moderate evidence for efficacy but with a limited clinical benefit, generally recommended
C	Insufficient evidence for efficacy or benefit does not outweigh the risk or the disadvantages (adverse events, costs, etc.), optional
D	Moderate evidence against efficacy or for adverse outcome, generally not recommended
E	Strong evidence against efficacy or for adverse outcome, never recommended

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