

국내 최초 수면개선 건강기능식품 [감태추출물]

KGC라이프앤진

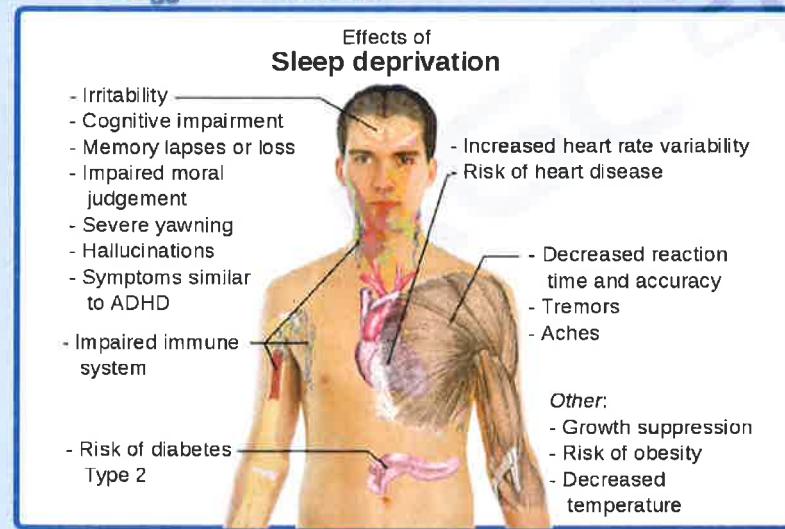


수면은 얼마나 중요한가?

(2/55)
2:27 PM

Importance of sleep

- Sleep accounts for 1/3 of human lifespan.
- Fundamental for body recovery and energy conservation.
- Related to immunity, CVD, learning, memory, obesity, and mood.



수면이 주는 10가지 놀라운 효과

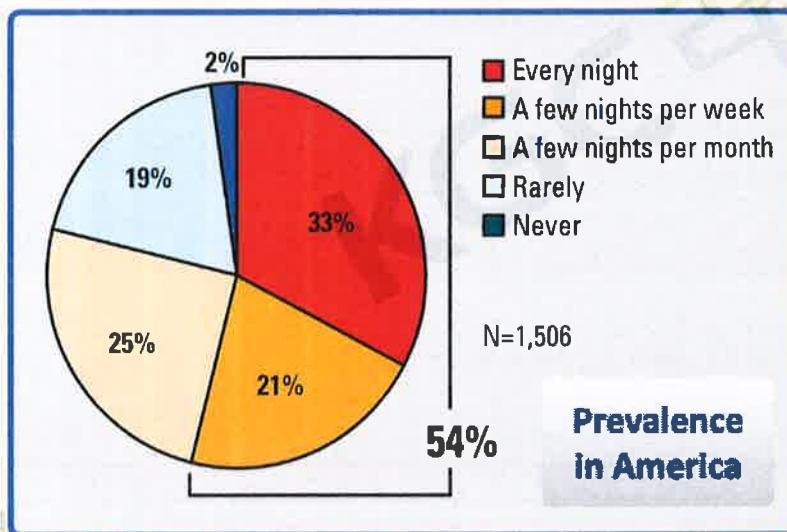
수명 ↑	기억력 ↑
면역력 ↑	집중력 ↑
자가치유능력 ↑	스트레스 ↓
신체능력 ↑	우울증 ↓
창의성 ↑	체중 ↓



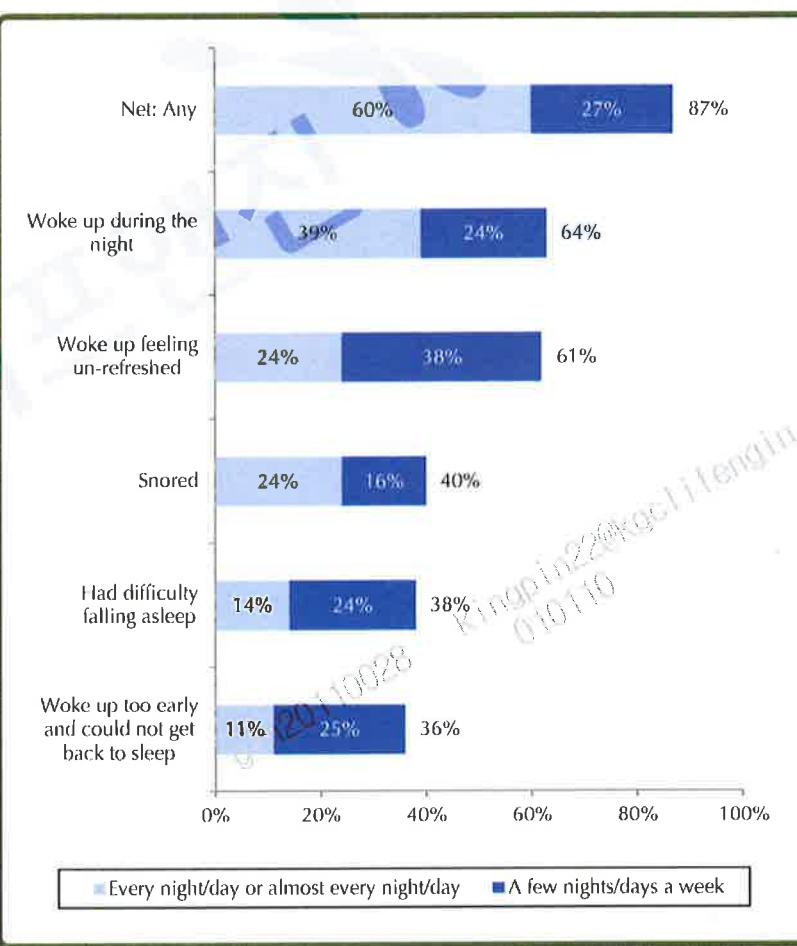
수면은 얼마나 중요한가?

Insomnia

- Insomnia is a very common complaint.
 - The global prevalence: 30-40%
 - Chronic insomnia: 10-15%
- Insomnia is defined as a sleep disorder associated with difficulty initiating or maintaining sleep.



미국의 수면장애 현황



Source: Harvard Medical School, 2008; National Sleep Foundation US, 2011.



여성, 노인, 우울증, 불안증과 수면장애

(4/55)
2:27 PM

여성



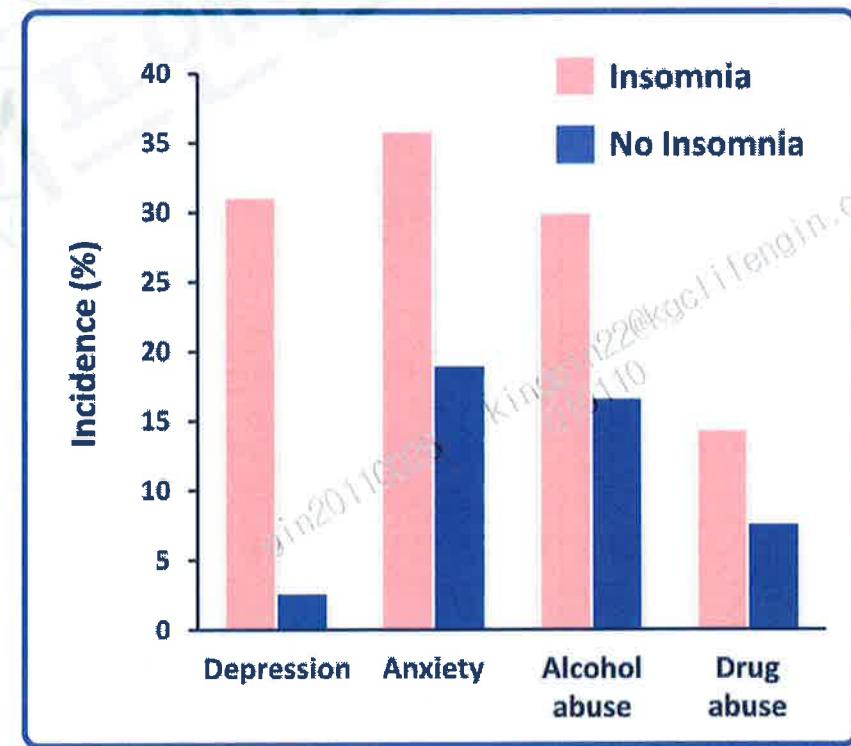
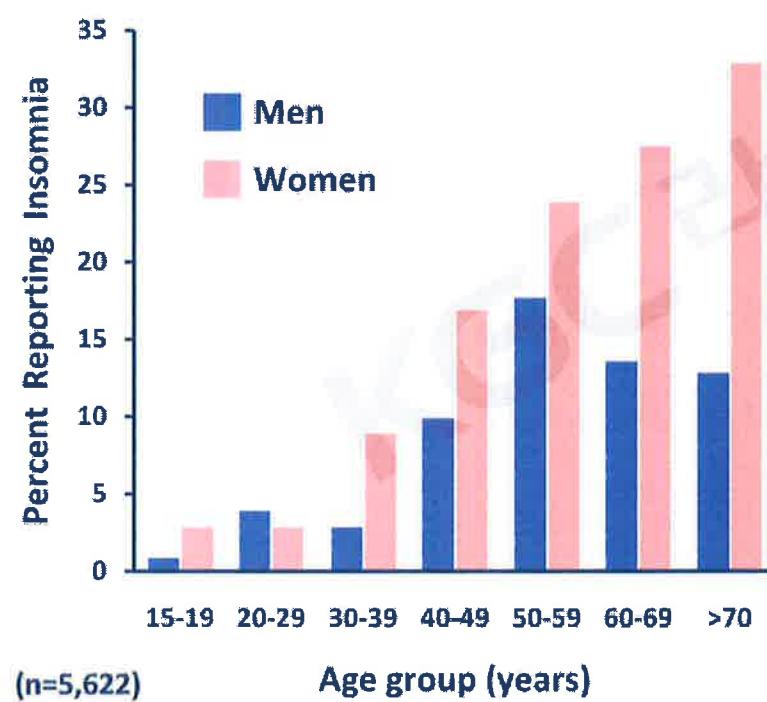
노인



우울증



불안증



Source : Ohayon, J Psychiatr Res, 1997 (Left); Breslau et al., Biol Psychiatry, 1996 (Right).



Sleeponomics (Sleep + Economics)

(5/55)
2:27 PM

The New York Times

2007 Nov.

American 'Sleeponomics'
\$20 billion

Sleep Disorders
Market to 2017, 2011

GBI Research
Global Business Intelligence

In 2010, the sleep disorders market
\$3.5 billion



companiesandmarkets.com

Sleeping Pills:
A Global Strategic
Business Report, 2010

The global sleeping pills market
\$9 billion by 2015

Sleep aids products in
the US market, 2008

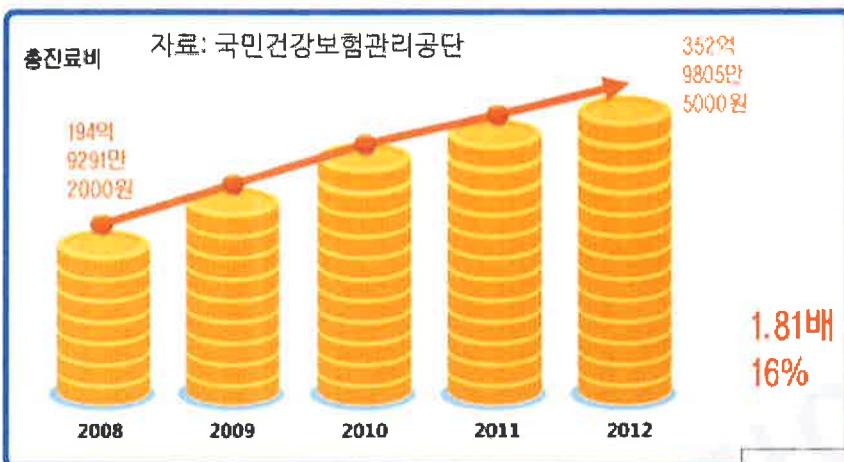


Packaged
Facts

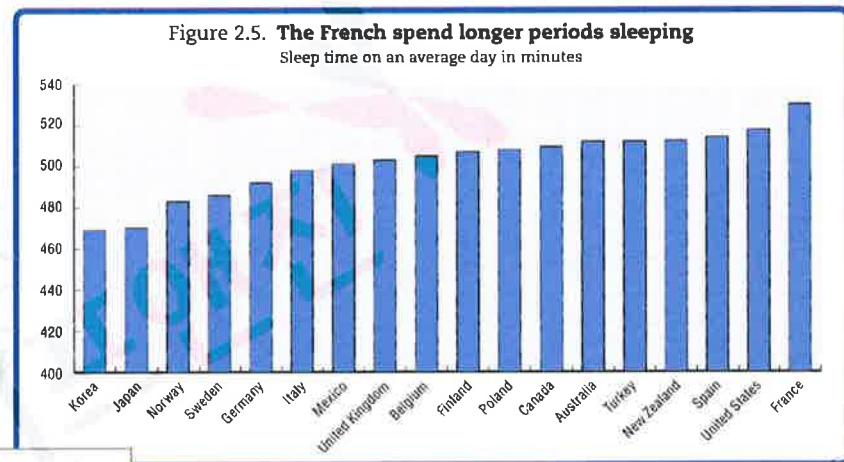
OTC sleep aids market
\$759 million by 2013.

우리나라의 수면

수면장애 진료비 급증



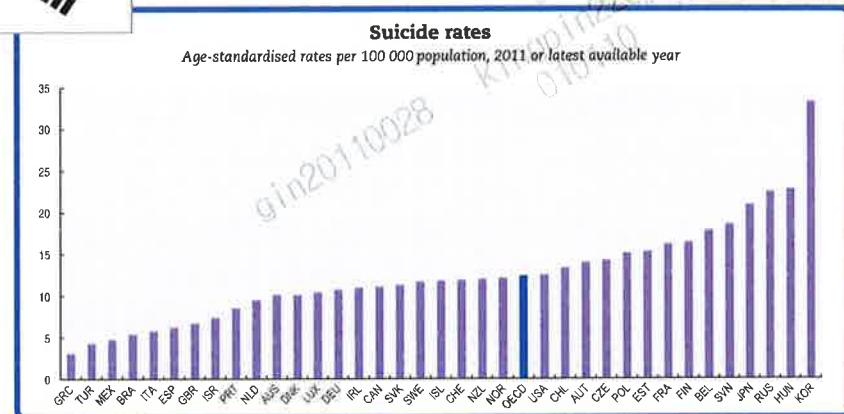
평균수면시간: OECD 꼴찌



근무시간: OECD 2위



자살률: OECD 1위





Sedative-hypnotics (Sleep drugs)

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2:27 PM

Class/Drug	Mechanism of action	Adverse effects
BZDs Estazolam, flurazepam, quazepam, triazolam	CNS effect due to allosteric interactions of BZD receptors with GABA_A receptors facilitating opening of chloride channels	Sedation, confusion, anterograde amnesia
Non-BZDs Zolpidem, zaleplon	Interact with GABA _A receptor complex at binding domains located near to or allosterically coupled to BZD receptors	Dizziness, somnolence
Antidepressants Trazodone	Weak but selective blockade of 5-HT reuptake at the presynaptic neuronal membrane; metabolite blocks CNS 5-HT₂ receptors	Weight changes, sweating, priapism
Amitriptyline	Blocks reuptake of NE and 5-HT at the neuronal membrane	Weight gain, bloating, CV changes
Mirtazapine	Antagonist at central presynaptic α_2 -adrenergic autoreceptors and heteroreceptors; antagonist at CNS 5-HT₂ and 5-HT₃ receptors	\uparrow Appetite, \uparrow serum Cholesterol, \uparrow TG
Antihistamines Diphenhydramine	First generation antihistamine that is an antagonist at the histamine H₁ receptor	Dizziness, somnolence

Innovation

Source : Borja and Daniel, Clinical Therapeutics 28, 2006.

Natural

Research

Sustainability

Drugs in development for insomnia

Drug name	Pharmacological action	Company	Develop. phase
Silenor® (doxepin)	Histamine H ₁ and H ₂ receptors antagonist	Somaxon	Approved
Ciltyri®, Eplivanserin	5-HT _{2A} antagonist	Sanofi-Aventis	US/EU decisions expected in 2009
ORG 50081 (esmirtazapine)	5-HT ₂ antagonist, histamine H ₁ antagonist	Schering-Plough	Phase III
Tasimelte, VEC-162	Melatonin receptor agonist	Vanda Pharmaceuticals	Phase III
Almorexant, ACT-078573	Orexin OX ₁ and OX ₂ receptors antagonist	Actelion	Phase III
Pimavanserin, ACP-103	5-HT _{2A} inverse agonist	Acadia	Phase II
PD-200,390	Voltage-gated calcium channel alpha(2)delta subunit modulator	Pfizer	Phase II
LY2624803, HY10275	5-HT _{2A} and histamine H ₁ antagonist	Eli Lilly, Hypnion	Phase II
TIK-301, LY156735	Melatonin agonist, 5-HT _{2C} antagonist	Tikvah Pharmaceuticals	Phase II



해외 수면개선 관련 식품

(9/55)
2:27 PM

- Due to the increase in insomnia, natural sleep aids are becoming more popular.
- More than 1.6 million American adults use natural sleep aids (National Health Survey, USA).
- Various commercial herbal sleep aids from land plants.



Valerian



Google scholar

valerian sleep

Search

Advanced Scholar Search

Scholar Articles excluding patents anytime include citations Create email alert Results 1 - 10 of about 10,700. (0.07 sec)

Aqueous extract of valerian root (*Valeriana officinalis L.*) improves sleep quality in man

PD Leathwood, F Chauffard, E Heck - *Pharmacology* ... , 1982 - Elsevier
The effect of an aqueous extract of valerian (*Valeriana officinalis L.*) root on sleep measures was studied on 128 people. Each person received 9 samples placebo, 3 containing 400 mg valerian extract and 3 containing a proprie

Cited by 203 - Related articles - All 5 versions

Valerian for sleep: a systematic review and meta-analysis

S Bent, A Padula, D Moore, M Patterson ... - *The American journal of ...*, 2006 - Elsevier
Insomnia affects approximately one-third of the adult population and contributes rates of absenteeism, health care use, and social disability. Extracts of the (*officinalis*) are widely used for inducing sleep and improving sleep quality. A

Cited by 110 - Related articles - All 7 versions



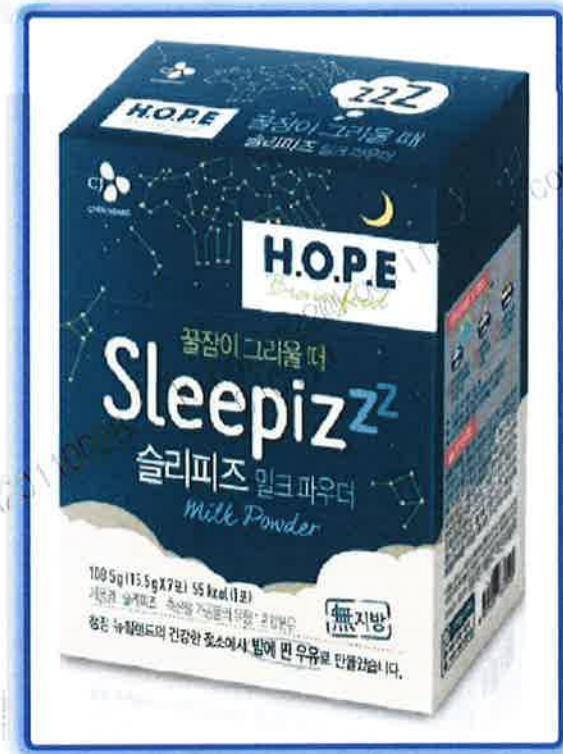
Valerian for Sleep: A Systematic Review and Meta-Analysis

Stephen Bent, MD,^{1,2} Amy Padula, MS,³ Dan Moore, PhD,⁴ Michael Patterson, HS,⁵ Wolf Mehling, MD,⁶
¹Other Center for Integrative Medicine, University of California, San Francisco; ²Department of Medicine, San Francisco Veterans Affairs Medical Center; ³Department of Epidemiology and Biostatistics, University of California, San Francisco;



국내 수면개선 관련 식품

(10/55)
2:27 PM



Innovation

Natural

Research



수면개선 건강기능식품의 전망

(11/55)
2:27 PM



반간강인

- 수면제 대체/보조
- 수면증진



건강인

- 수면증진

고령화 시대

스트레스와 걱정

건강 장수

우울증

웰빙과 힐링

불면증 등 수면장애

바쁘고 복잡한 사회

자살



수면개선 감태추출물 개발 과정

(12/55)
2:27 PM

한국식품연구원



- 연구 시작 (2010)
- 감태 수면개선 효과 확인
- 국내외 특허 출원 및 등록



KGC라이프앤진



- 12년 5월 XR시크릿 출시
- 성기능 개선 기능성
- 섭취 후 “숙면” 효과 확인

2012년 기술이전 계약 → 개별인정 추진





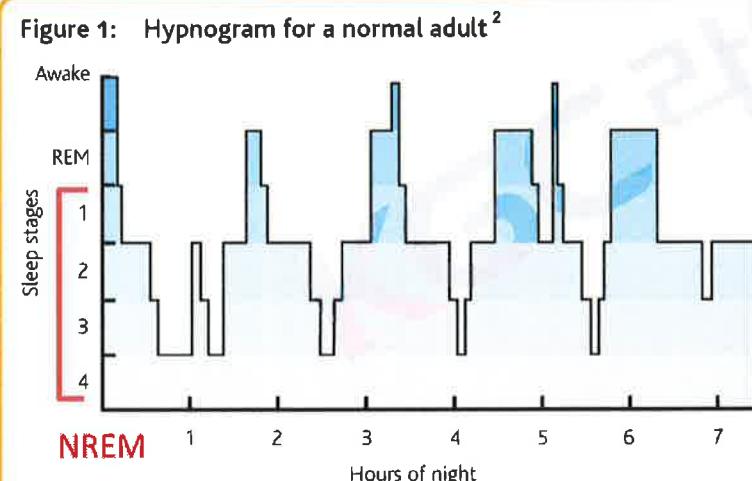
Sleep stages

(13/55)
2:27 PM

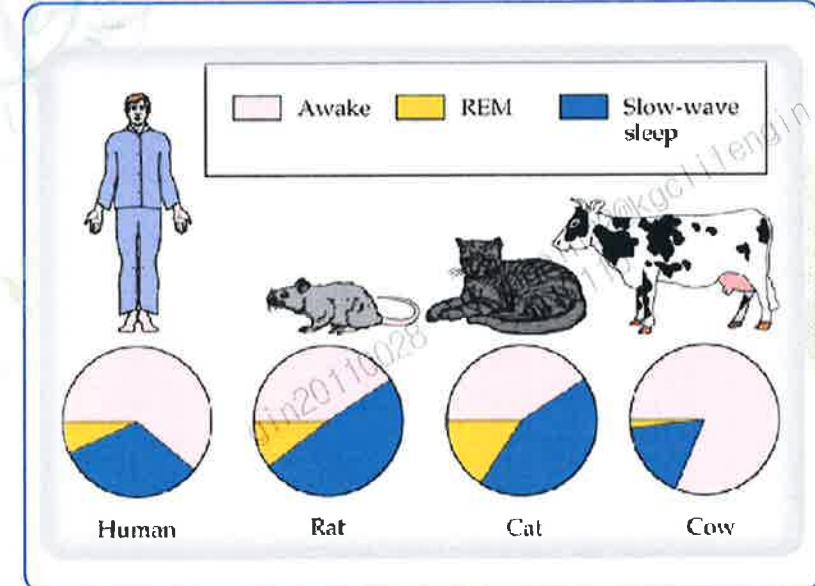
- Two alternating types of sleep : NREM and REM

- NREM (Non-Rapid Eye Movement): 75% of sleeping time, stage 3-4: slow wave sleep
- REM (Rapid Eye Movement) : 25% of sleeping time, paradoxical sleep

Typical sleep structure of human



Sleep structures for animals



Innovation

Natural

Research

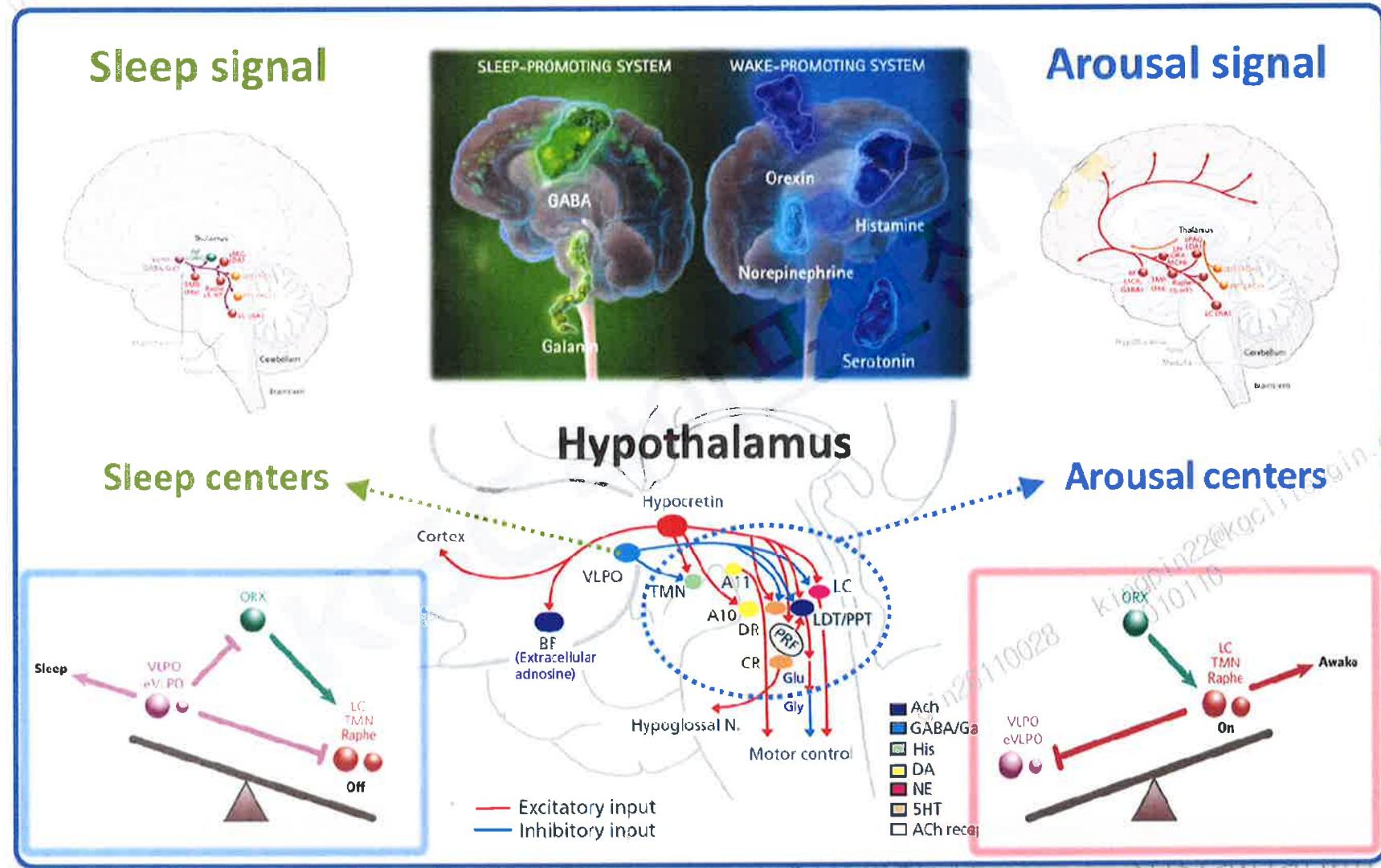
Sustainability

Source : Erman, J Clin Psychiatry 62, 2001.



Sleep regulation

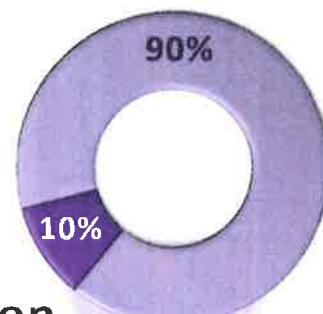
(14/55)
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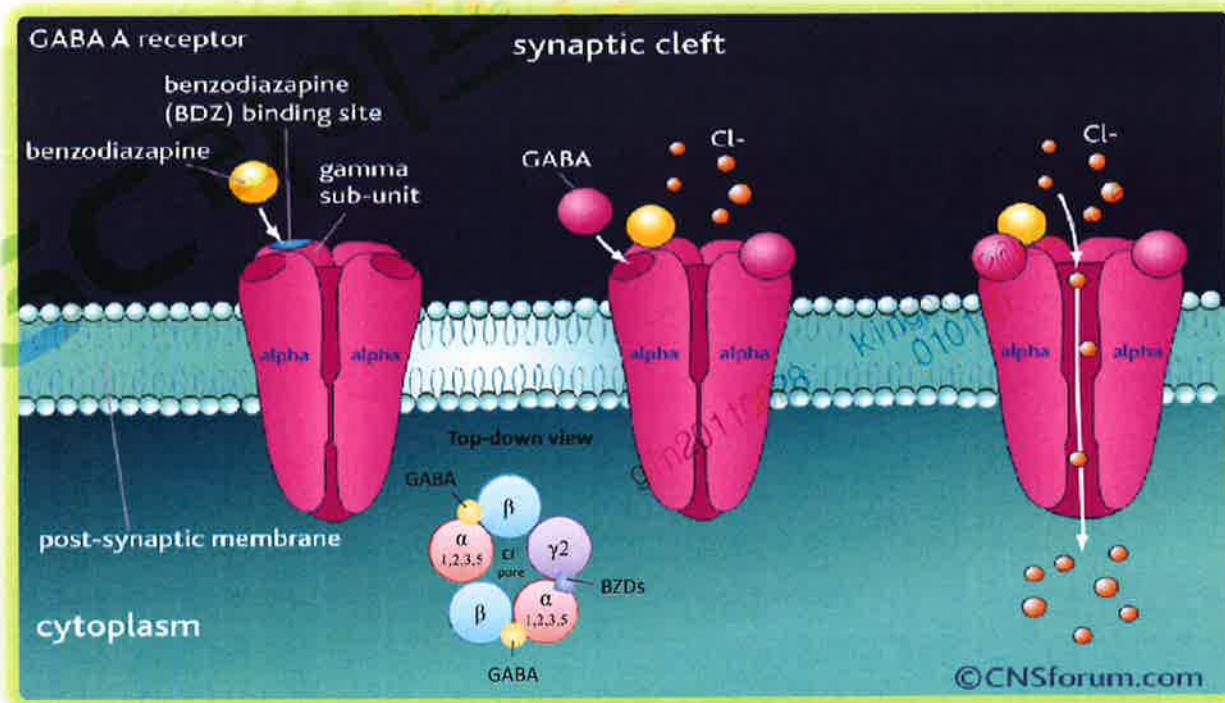
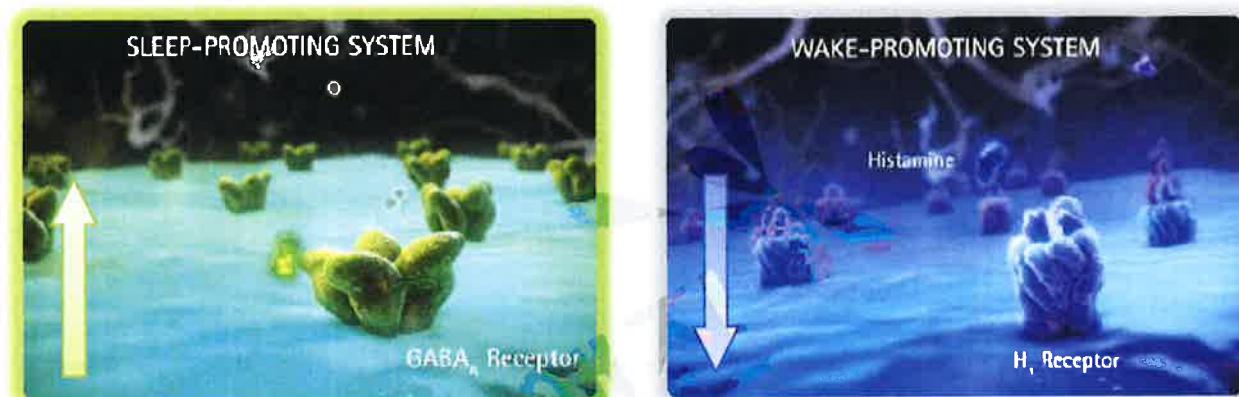
Source : Saper et al., Nature 437, 2005; Mignot et al., Nature Neuroscience supplement 5, 2002.

Hypnotic mechanism

Non-neuron (Glia)



Neuron



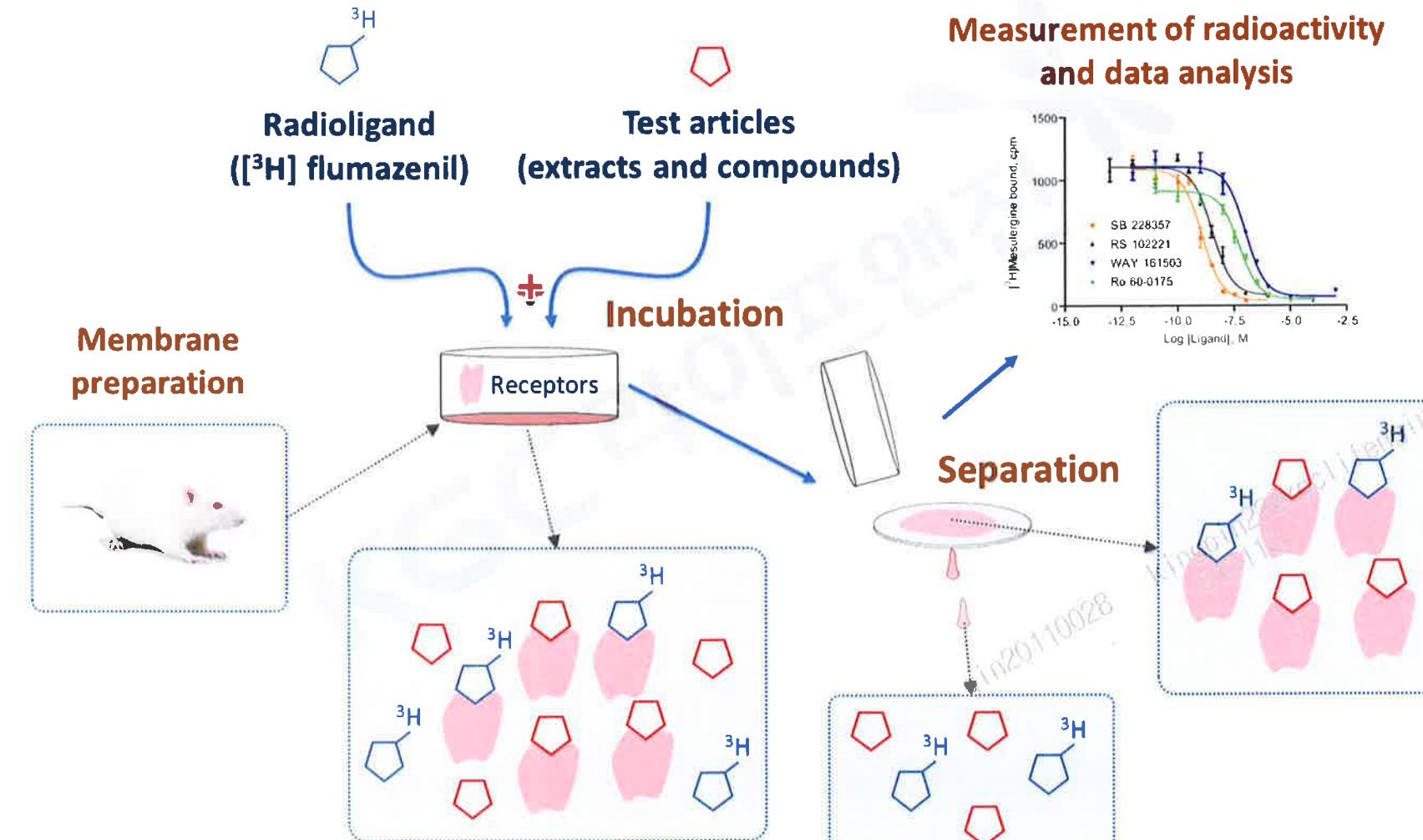
Source : CNS forum.



In vitro 활성 평가방법

(16/55)
2:27 PM

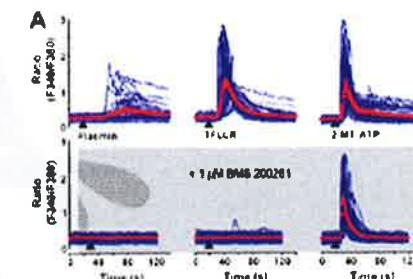
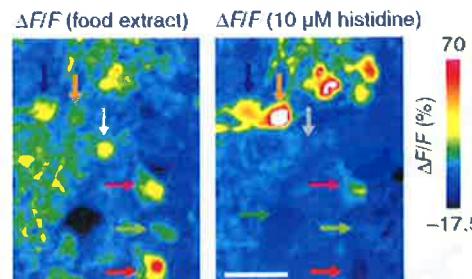
신경전달물질 수용체 결합활성 (Receptor binding assay)



In vitro 활성 평가방법

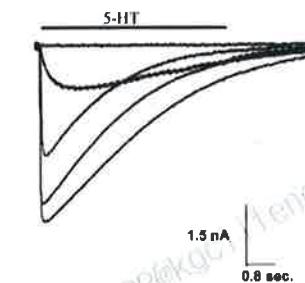
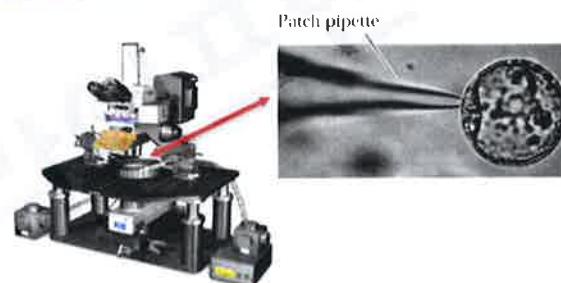
Ca²⁺ imaging

- 칼슘을 감지할 수 있는 형광물질을 세포 내에 투입하여 칼슘농도를 측정
- GPCR 수용체의 활성화에 따른 세포내 칼슘 증가량 분석 가능



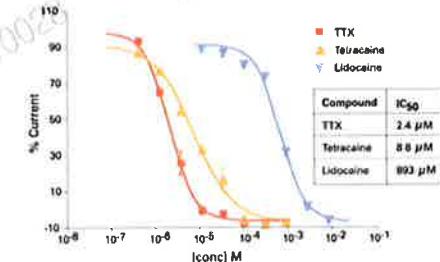
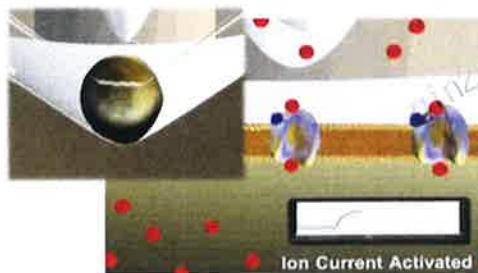
Patch clamp

- Ion channel의 활성도를 가장 정확하게 측정할 수 있는 technique
- 단일 세포 내의 전기적 변화를 측정할 수 있어 single channel 수준의 분석이 가능



Voltage clamp

- 개구리 난모세포(oocyte)에 수용체 RNA를 injection하여 발현시킴
- 발현된 ion channel의 활성도를 전류의 흐름으로 분석





동물 수면유도 실험 (pentobarbital)

(18/55)
2:27 PM

Experimental procedure

male ICR mouse (20–25 g)

Adaptation

7 days

Fasting

1 day

Experiment

Samples (p.o.)

45 min

Pentobarbital (i.p.)

1:00 pm

Sleep duration

Acceleration test



Judgment of sleep and wake

← Loss of righting reflex (sleep)

Recovery of righting reflex (wake) →

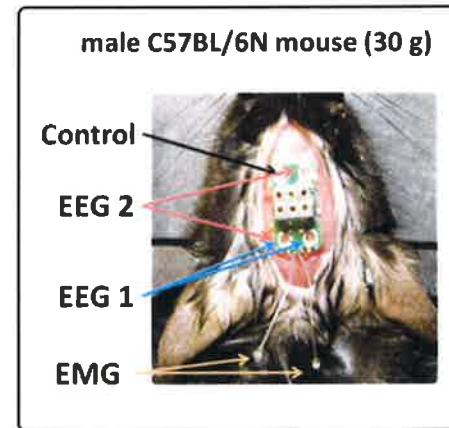




동물 수면구조 분석 (EEG & EMG)

(19/55)
2:27 PM

[Surgery]



Experimental procedure

EEG: electroencephalogram
EMG: electromyogram

Surgery and recovery

7 days

Adaptation

(recording condition)

4 day

Vehicle
(baseline)

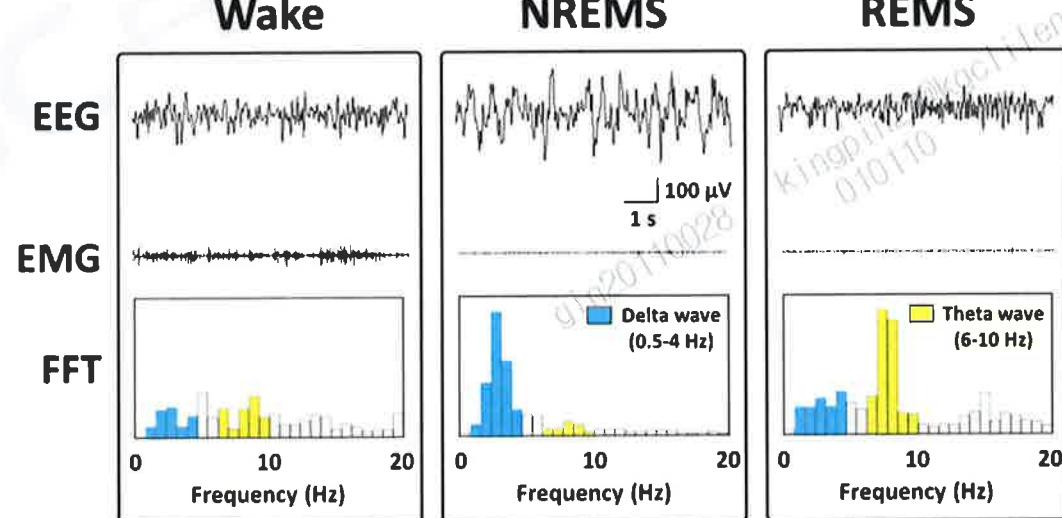
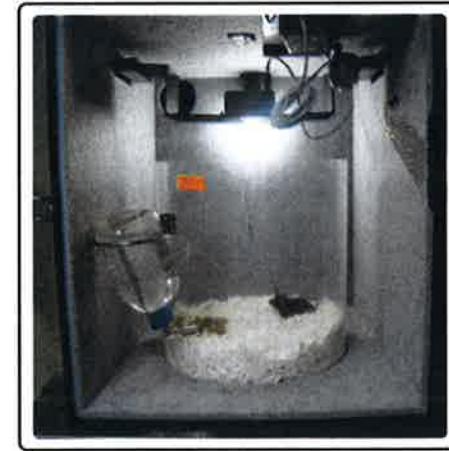
5 pm

Drug
treatment

5 pm

1st day (24 h) 2nd day (24 h)

[Recording]





Clinical Trials (인체적용시험)

(20/55)
2:27 PM

Polysomnography (PSG)

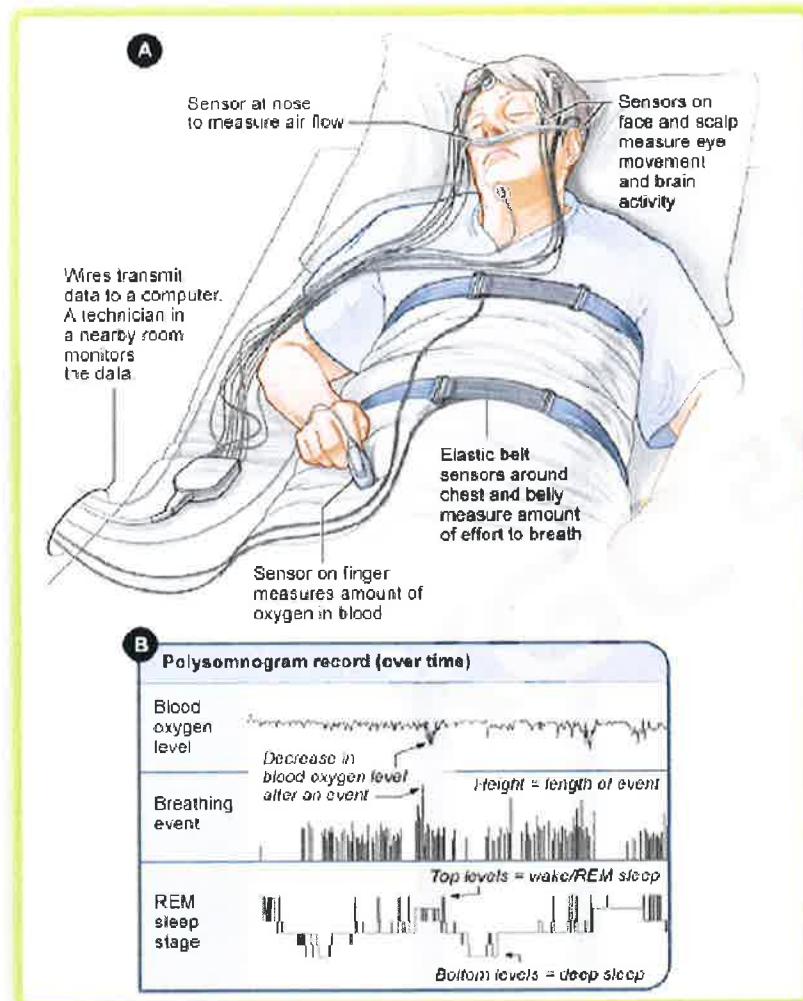
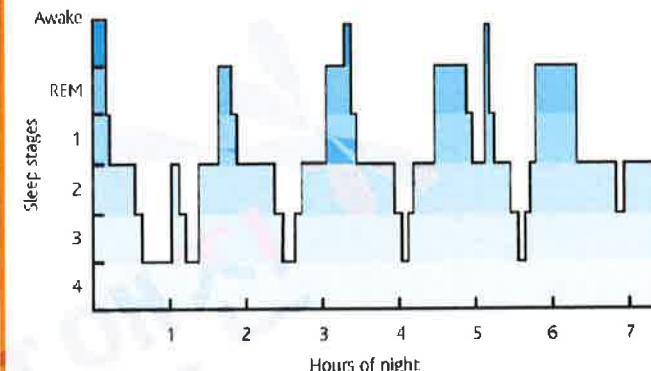


Figure 1: Hypnogram for a normal adult²



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Sleep Medicine Institute

HOME

UPMC LEADERSHIP FACILITY

FACULTY

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INSTRUMENTS

- [Dayton Insomnia Symptom Scale \(DISS\)](#)
- [Insomnia Symptom Questionnaire \(ISQ\)](#)
- [Pittsburgh Insomnia Rating Scale \(PIRS\)](#)
- [Pittsburgh Sleep Quality Index \(PSQI\)](#)

PUBLICATIONS

LINKS

RESEARCH

RESEARCH STUDIES

TRANSLATIONAL RESEARCH TRAINING IN SLEEP MEDICINE (T32)

CLINICAL RESOURCES

PITTSBURGH SLEEP MEDICINE IN THE NEWS

Instruments

► [Pittsburgh Sleep Quality Index \(PSQI\)](#)

Please cite the reference for the PSQI (see below) in any publications. If you intend to reproduce the article in which the instrument was published, we recommend that you also contact Elsevier Science Ireland Ltd., the publisher of Psychiatry Research. Any questions regarding reprinting of the article should be directed to Permissions Department, Elsevier Science Ireland Ltd., Elsevier House, Brookvale Plaza, East Park, Shannon, Co. Clare, Ireland; Fax +353 61 709620; or via e-mail.

Attached is the PSQI, the correct scoring algorithm, the original article, and the scoring database.

Hynan, S. L., Reynolds, C. F., Monk, T. H., Hallman, K. R., & Kupfer, D. J. (1998). The Pittsburgh Sleep Quality Index (PSQI): A new instrument for psychiatric research and practice. *Psychiatry Research*, 26(2), 163-213. The detailed scoring instructions are at the end of this journal article.

The PSQI has been translated into 66 additional languages. For more information on these languages, follow the link to the NAI website ([Click here to download the user agreement](#)) and to request the PSQI in a different language.

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Collaboration

(21/55)
2:27 PM

최종
목표

수면 개선 건강기능식품 개발

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기능성식품연구본부
조승목



Fudan University
State Key Laboratory of Medical Neurobiology
Prof. Huang



Seoul Sleep Center
서울수면센터
한진규



Tsukuba University
International Institute for Integrative Sleep medicine
Prof. Urade

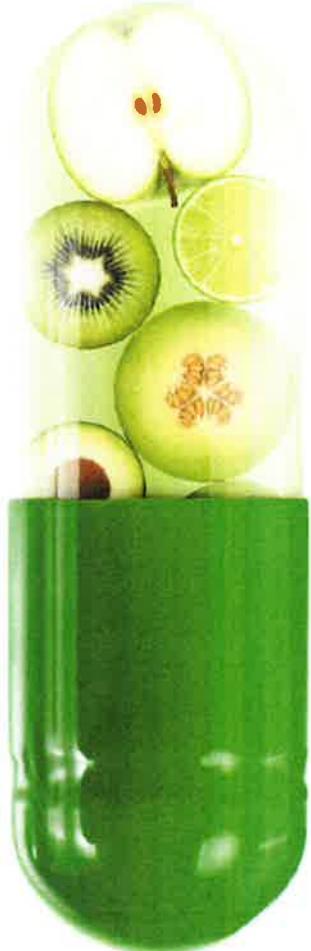


경희대학교
KYUNG HEE UNIVERSITY
한방재료학과
백남인

Innovation

Natural Research

Sustainability



감태 연구 결과



주요 후보 소재

(23/55)
2:27 PM

연구 목적 국내 식품소재의 수면개선 효능 및 작용기작을 규명하고
산업화 연구를 통해 개별인정형 건강기능식품을 개발하고자 함

다소비식품 (200)

육상식물 (400)

해양식물 (50)

쌀

(Oryza sativa)



감초

(Glycyrrhiza glabra)



감태

(Ecklonia cava)



INNOVATION

NATURE

RESEARCH

SUSTAINABILITY

주요 연구 성과

Journal of Ethnopharmacology 132 (2010) 223–232
Content lists available at ScienceDirect
Journal of Ethnopharmacology
journal homepage: www.elsevier.com/locate/jethpharm

Hypnotic effects and binding studies for GABA_A and 5-HT_{2C} receptors of traditional medicinal plants used in Asia for insomnia

Sueng-Mock Cho^{a,b}, Makoto Shimizu^b, C. Justin Lee^c, Dae-Seok Han^d, Cheol-Kyun Jung^a, Jin-Mo Kim^a, Joo-Hyung Kim^a, Hyun-Jin Kim^a, You-Jin Jeon^e, Young-Ho Jin^f, Nam-In Baek^f, Dong-Soo Kim^d, Dong-Sub Kim^d, Chang-Won Cho^a, Ji-Hae Park^d, Ae-Nim Pae^e, Daeseok Han^d, Dong-Sub Kim^d, Kyung-Hee Kim^d

Received 20 September 2009; Accepted 14 January 2010
DOI 10.1016/j.jethpharm.2009.12.060-8

RESEARCH NOTE

Effect of the Licorice Flavonoid Isoliquiritigenin on the Hypnotic Effects of Licorice Extract and Its Major Flavonoid Constituents in Mice

Suengmok Cho, Minseok Yoon, Dongsoo Kim, Jin-Soo Kim, Heyjin Yang, Seo-Young Kim, Dong-Sub Kim, Chang-Won Cho, Ji-Hae Park, Ae-Nim Pae, Daeseok Han, Dong-Sub Kim, Kyung-Hee Kim

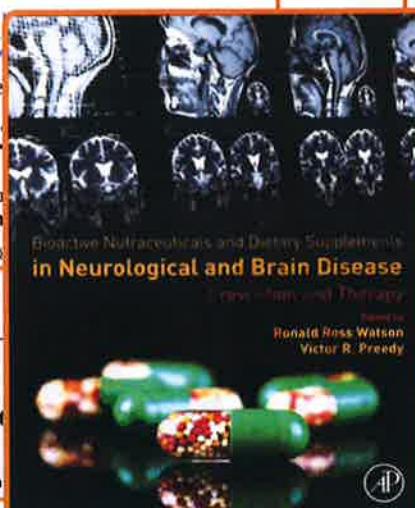
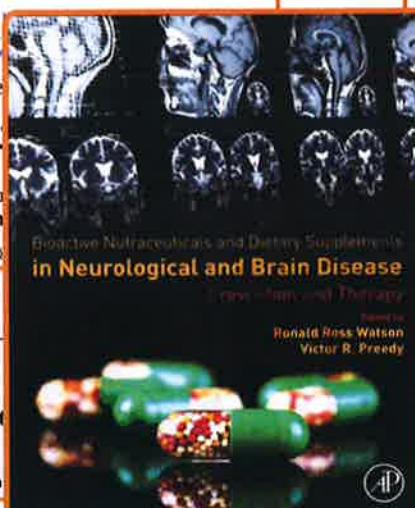
Biological and Biophysical Research Communications
journal homepage: www.elsevier.com/locate/ybbrc

Contents lists available at SciVerse ScienceDirect
Biochemical and Biophysical Research Communications
journal homepage: www.elsevier.com/locate/ybbrc

Isoliquiritigenin, a chalcone compound, is a positive allosteric modulator of GABA_A receptors and shows hypnotic effects

Suengmok Cho^{a,b}, Sojin Kim^c, Zhenhua Jin^c, Heyjin Yang^a, Daeseok Han^a, Nam-In Baek^d, Jinho Jo^a, Chang-Won Cho^a, Ji-Hae Park^d, Makoto Shimizu^{b,*+1}, Young-Ho Jin^{c,+1}

*Korea Food Research Institute, Seongnam 463-740, Republic of Korea
†Department of Applied Biological Chemistry, The University of Tokyo, Tokyo 113-0033, Japan
‡Department of Physiology, School of Medicine, Kyung Hee University, Seoul 120-701, Republic of Korea
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Food Chemistry 132 (2012) 1133–1142
Content lists available at SciVerse ScienceDirect
Food Chemistry
journal homepage: www.elsevier.com/locate/foodchem

Food Chemistry 132 (2012) 1133–1142
Content lists available at SciVerse ScienceDirect
Food Chemistry
journal homepage: www.elsevier.com/locate/foodchem

Phlorotannins of the edible brown seaweed *Ecklonia cava* Kjellman induce sleep via positive allosteric modulation of gamma-aminobutyric acid type A-benzodiazepine receptor: A novel neurological activity of seaweed polyphenols

Suengmok Cho^{a,b}, Hyun-Jin Kim^a, You-Jin Jeon^e, C. Justin Lee^c, Young-Ho Jin^f, Nam-In Baek^f, Dong-Sub Kim^d, Chang-Won Cho^a, Ji-Hae Park^d, Ae-Nim Pae^e, Daeseok Han^d, Dong-Sub Kim^d, Kyung-Hee Kim^d

Received 12 December 2011; Accepted 10 January 2012
DOI 10.1016/j.foodchem.2012.01.040

ORIGINAL INVESTIGATION

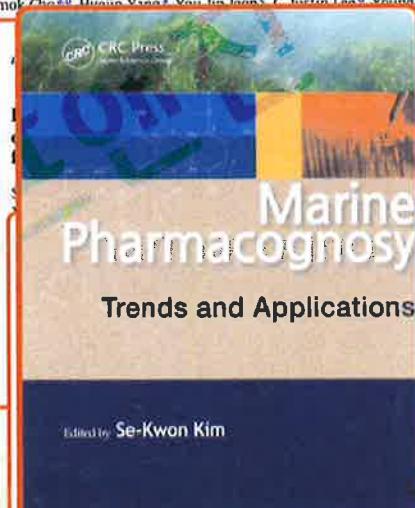
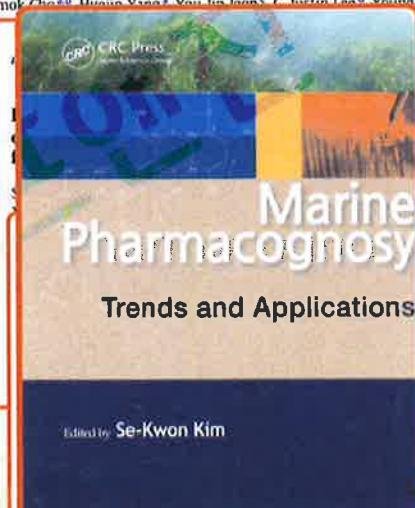
Marine polyphenol phlorotannins promote non-rapid eye movement sleep in mice via the benzodiazepine site of the GABA_A receptor

Suengmok Cho^a, Minseok Yoon^a, Ae-Nim Pae^e, Young-Ho Jin^f, Nam-Chul Cho^f, Yoko Takata^f, Yoshihiro Urade^f, Sojin Kim^c, Jin-Soo Kim^c, Heyjin Yang^a, Jlyoung Kim^c, Jinkyung Kim^c, Jin-Kyu Han^c, Makoto Shimizu^b, Zhi-Li Huang^c

Received 9 October 2013; Accepted 8 January 2014
DOI 10.1016/j.foodchem.2014.01.3445-1

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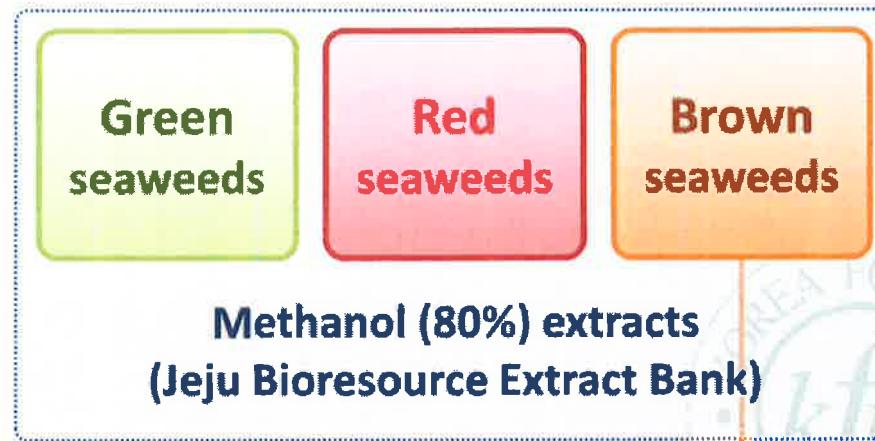
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Screening

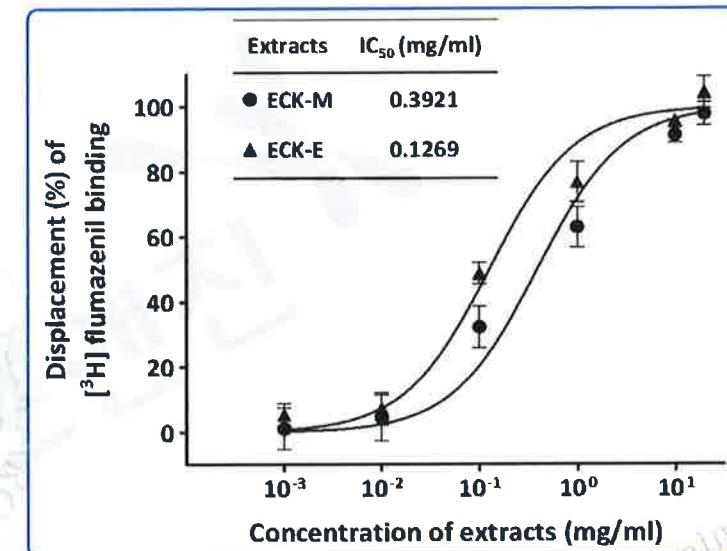
(25/55)
2:27 PM



GABA_A-BZD receptor binding assay

Ecklonia cava (EC)

- The edible brown seaweed *E. cava* is distributed in the coastal areas of Korea and Japan.
- One of the major seaweeds utilized industrially in Jeju island of Korea.



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Optimization of extraction conditions

(26/55)
2:27 PM

Response surface methodology (RSM)

[Independent variables]

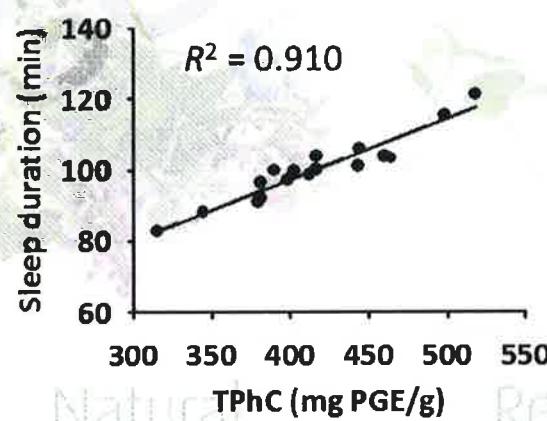
Independent variables	Symbol	Range and levels					
		-1.682	-1	0	1	+1.682	
Ethanol concentration (% , v/v)	X_1	55	63	75	87	95	
Extraction temperature (°C)	X_2	40	48	60	72	80	
Extraction time (h)	X_3	6	9.6	15	20.4	24	

[Dependent variables]

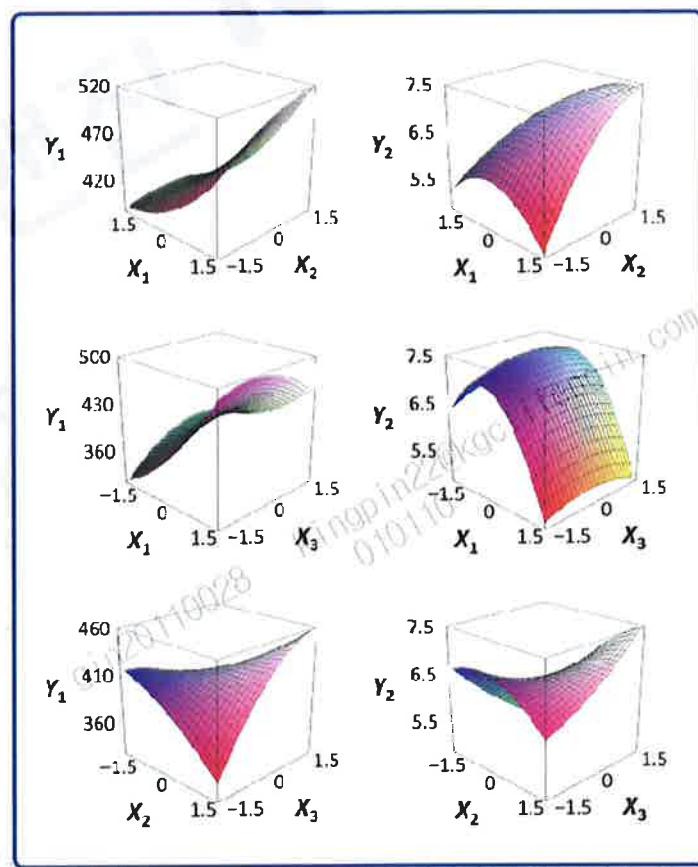
Y_1 : Total phlorotannin
content (TPhC)

Y_2 : Yield of phlorotannins

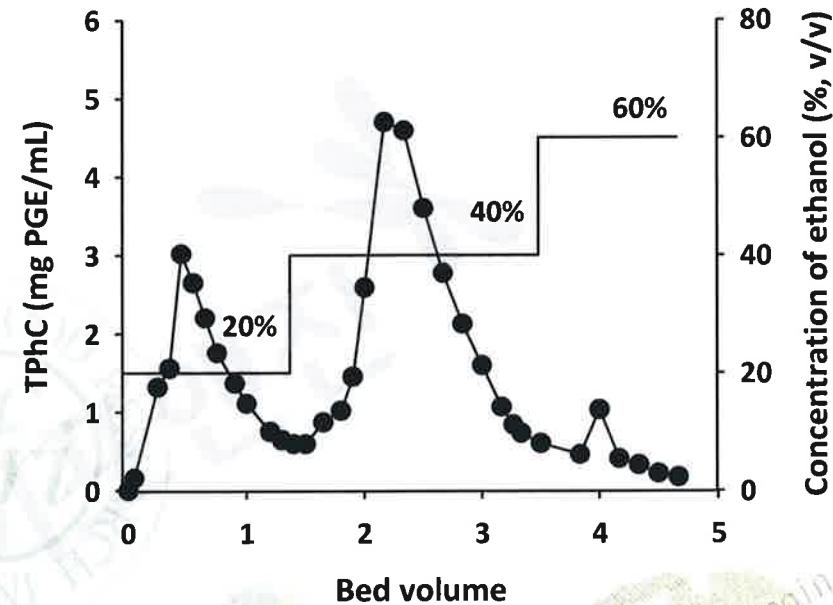
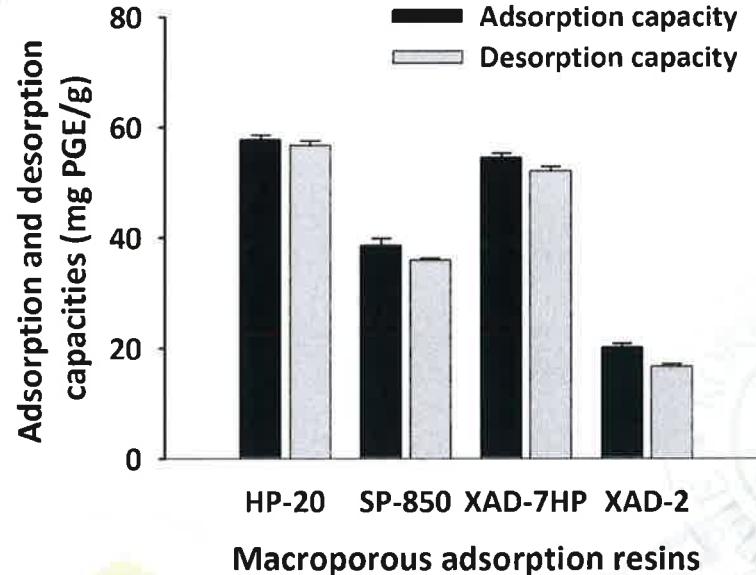
Y_3 : Sleep duration



[3D response model plots]



Purification of phlorotannins (PRT)

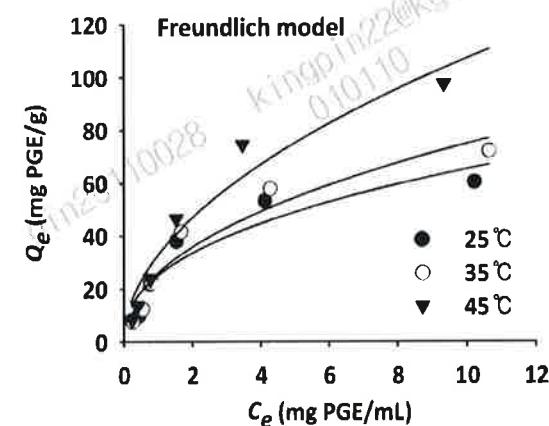
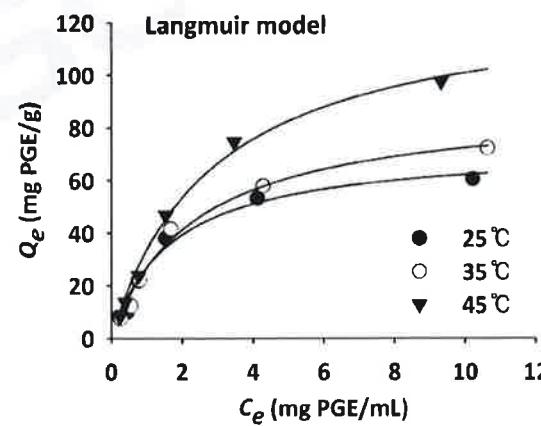


Langmuir (45°C)

$$Q_e = \frac{(129.70)}{(2.848 + C_e)} \quad (R^2=0.9947)$$

Freundlich (45°C)

$$Q_e = 32.96^{0.5128} \quad (R^2=0.9471)$$

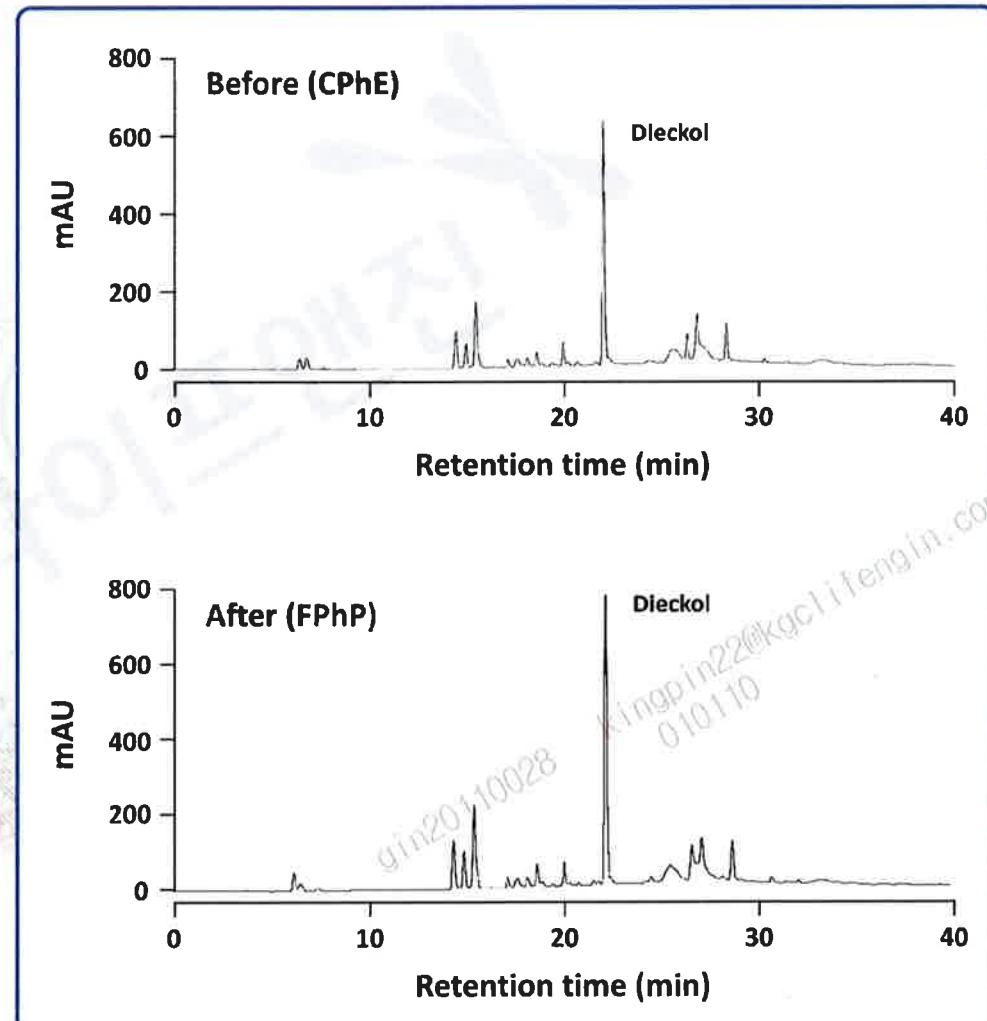




Purification of phlorotannins (PRT)

Results
(28/55)
2:27 PM

Sample	CPhE	FPhP
TPhC (mg PGE/g)	452±10.1	905±12.7
Dieckol (mg/g)	51.8±3.8	85.6±2.4
Arsenic (μ g/g)	180±2.2	48±1.3



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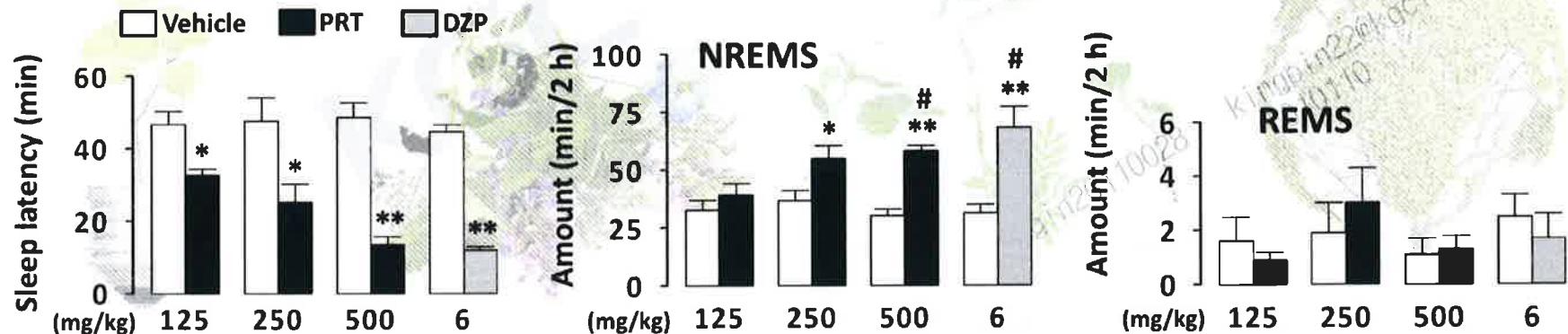
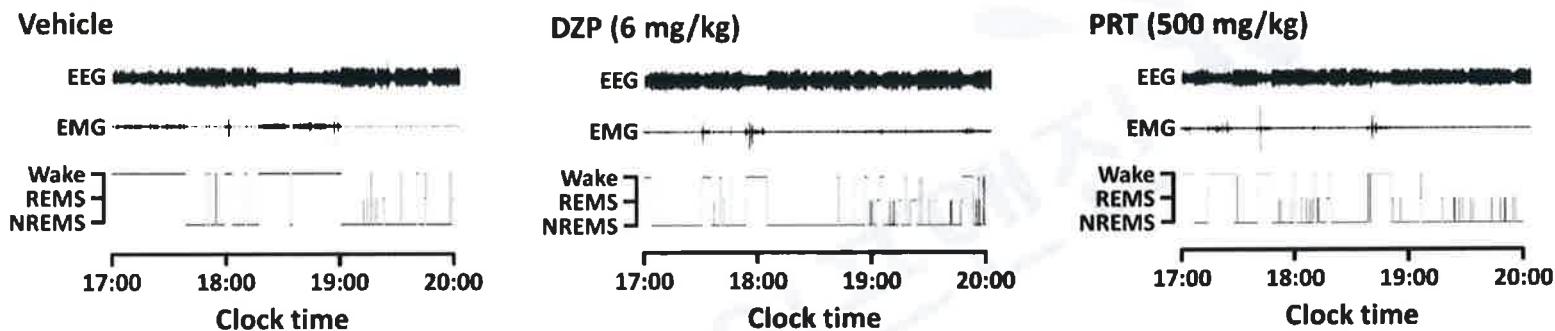
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Effects of PRT on sleep profiles

(29/55)
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[Representative examples of EEG and EMG signals and corresponding hypnograms]



Source: Cho et al., Psychopharmacology, 2014.

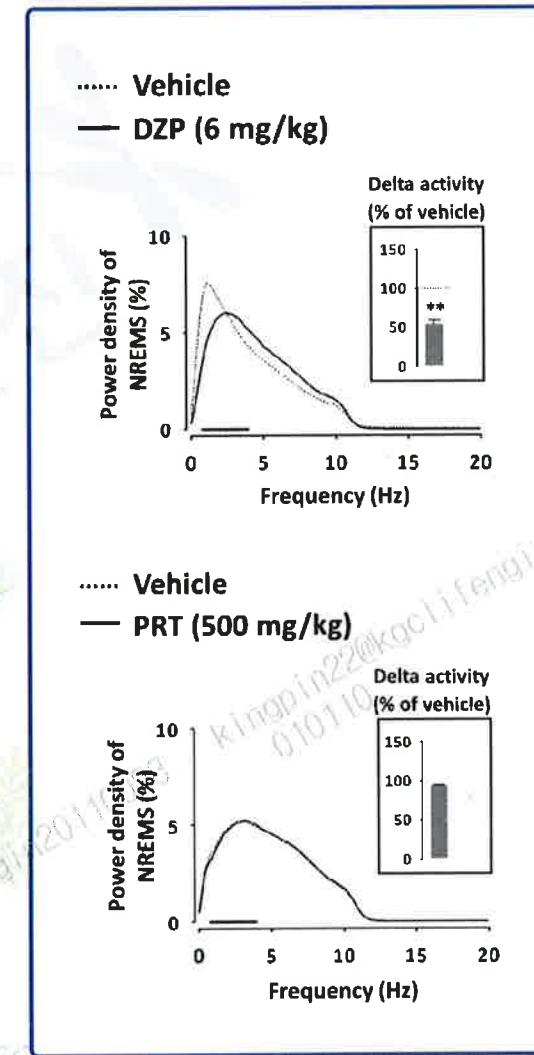
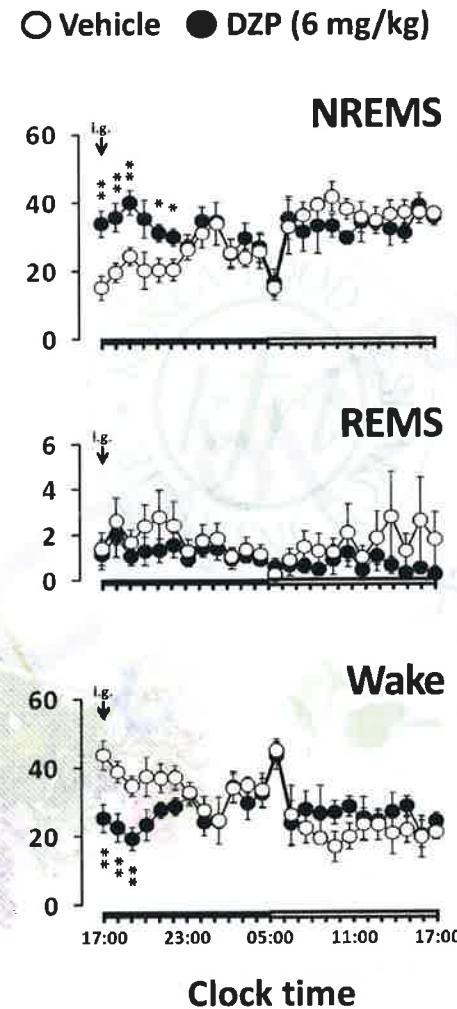
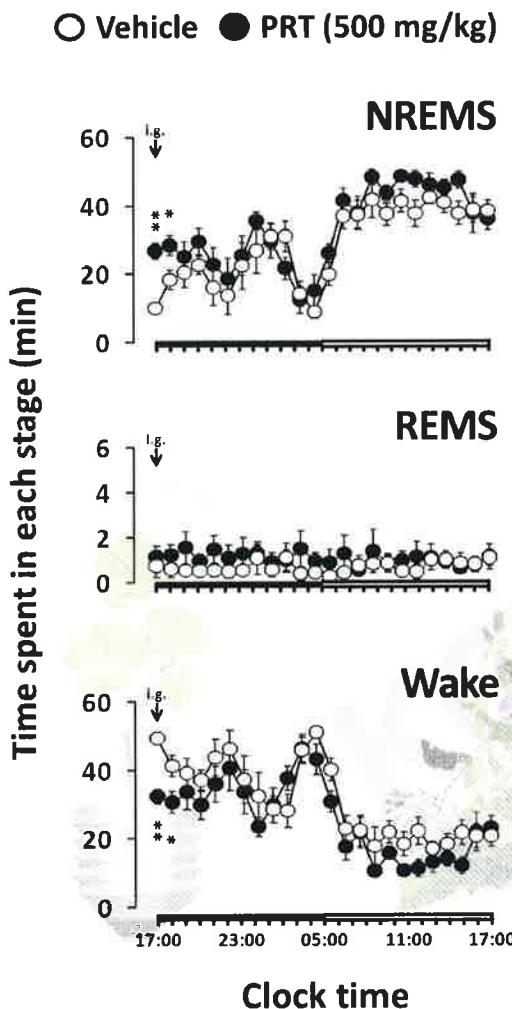
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Effects of PRT on sleep profiles



Source: Cho et al., Psychopharmacology, 2014.



감태추출물의 수면개선 효과

(31/55)
2:27 PM

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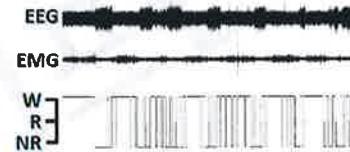
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A

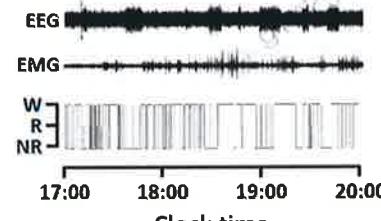
[Vehicle]



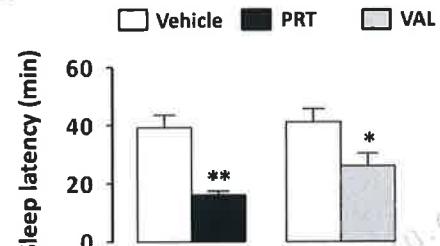
[PRT, 500 mg/kg]



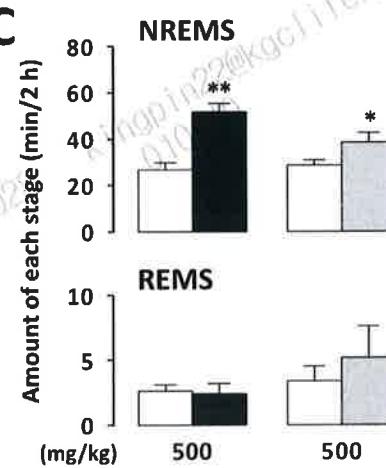
[VAL, 500 mg/kg]



B



C



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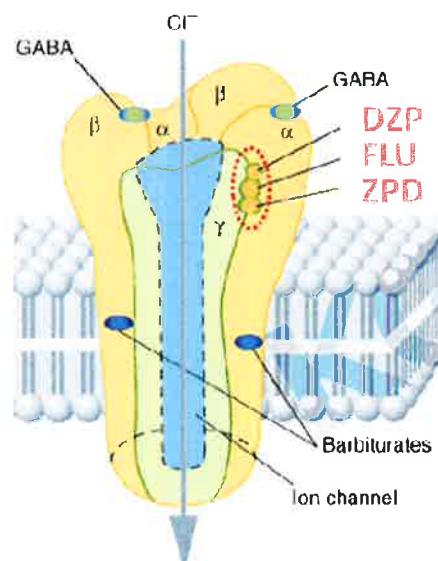
GABAergic mechanism of PRT

[Ligands for BZD site]

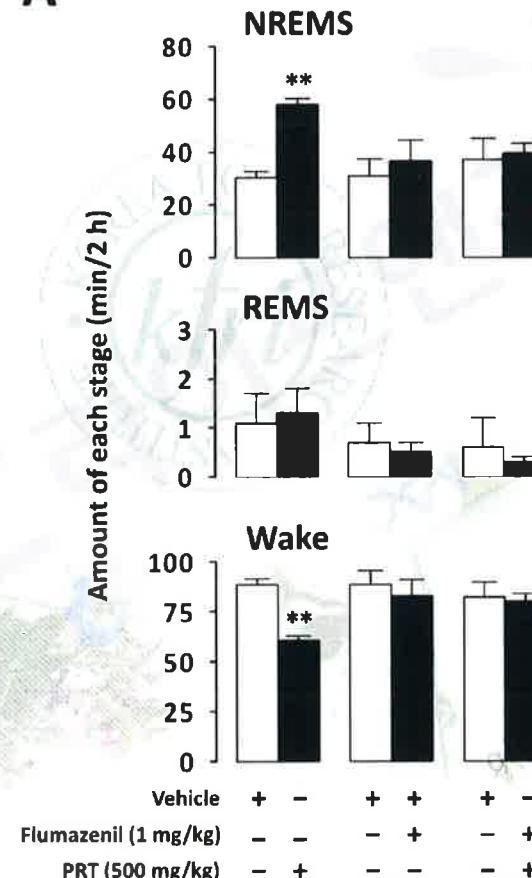
Agonist: BZD (Diazepam, DZP)

Non-BZD (Zolpidem, ZPD)

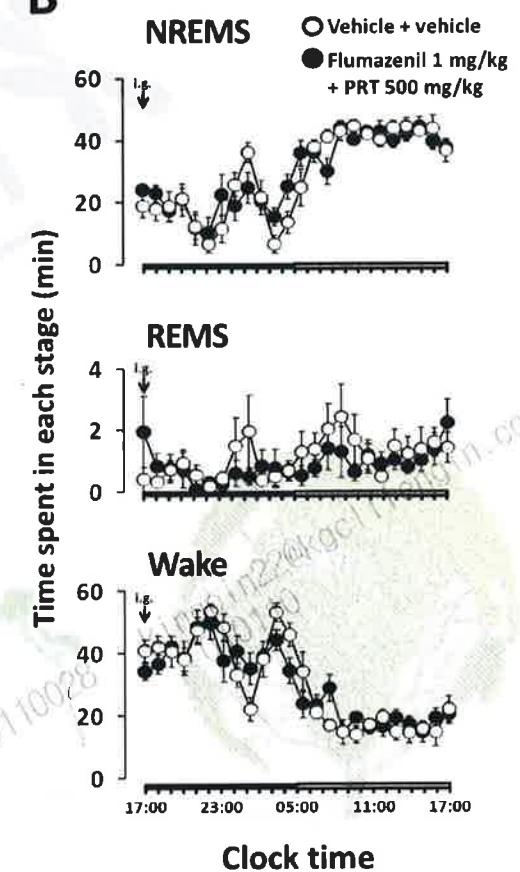
Antagonist: Flumazenil (FLU)



A



B



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Source: Cho et al., Psychopharmacology, 2014.

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GABAergic mechanism of PRT

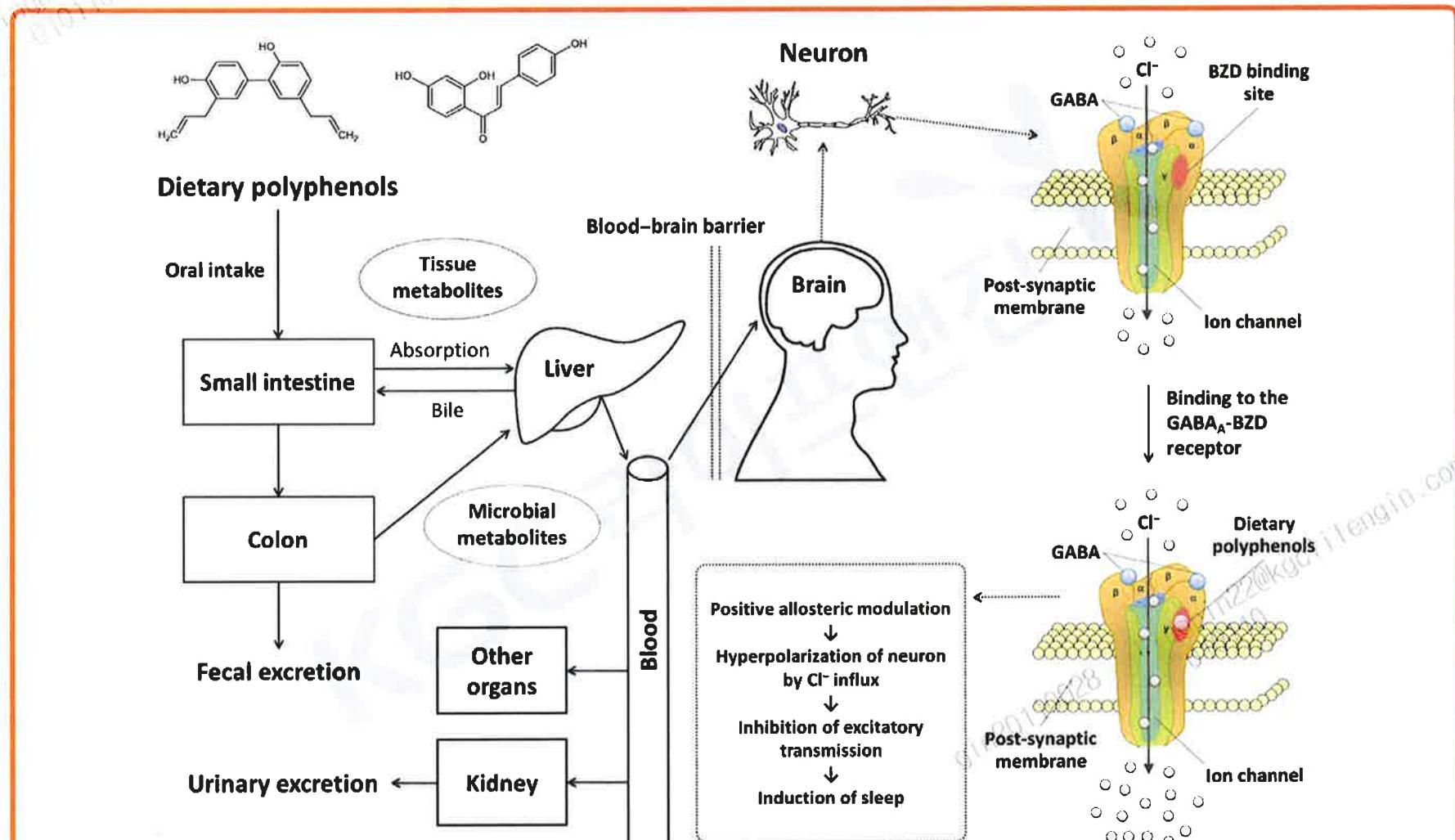
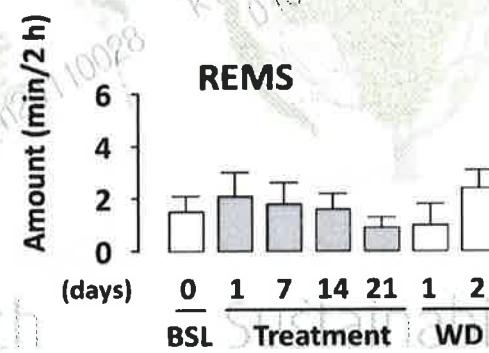
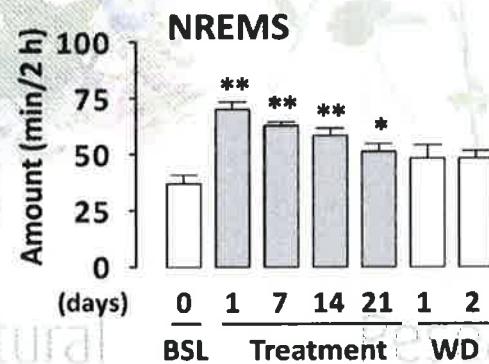
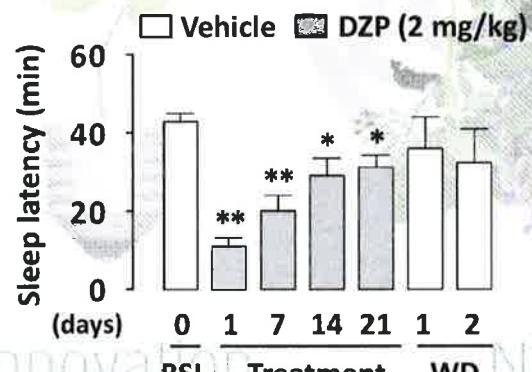
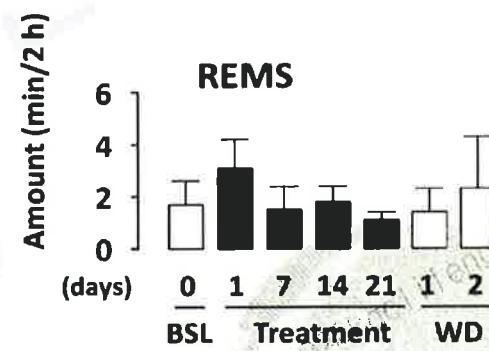
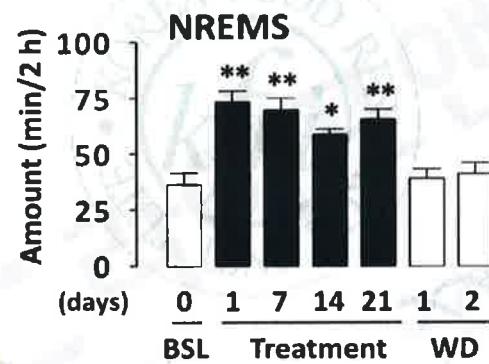
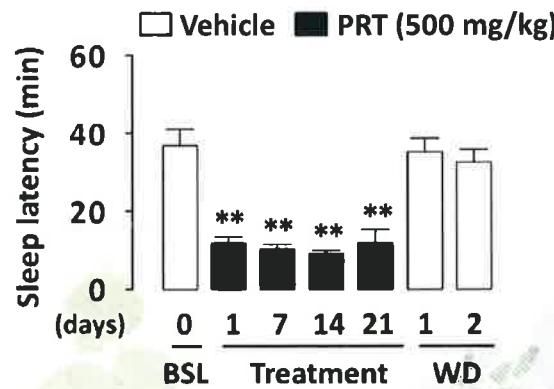
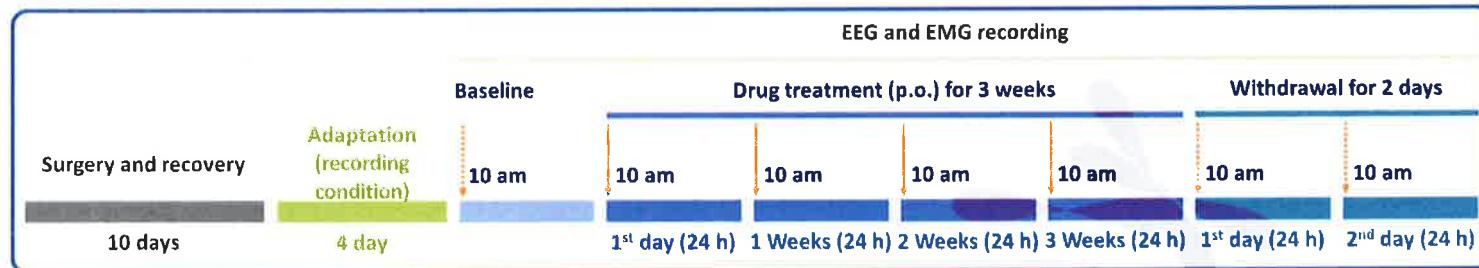
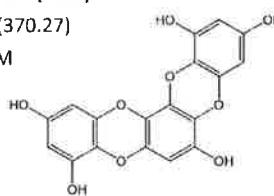
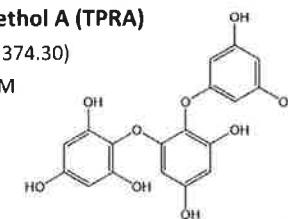
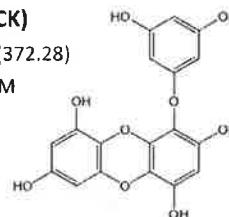
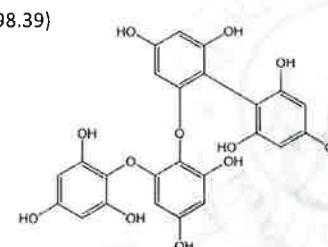
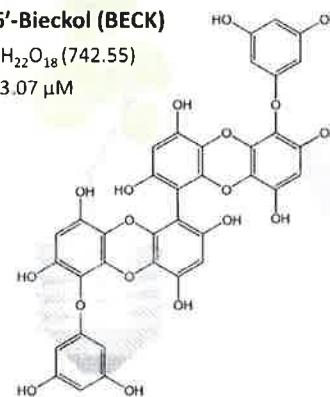
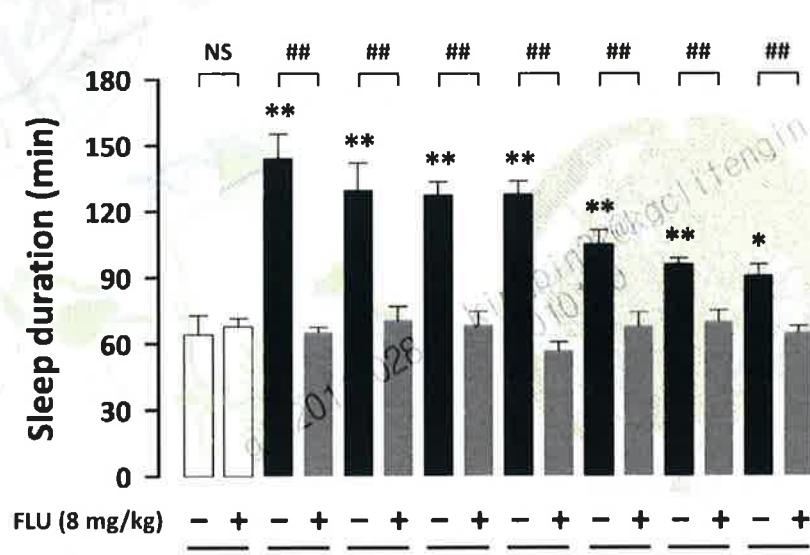
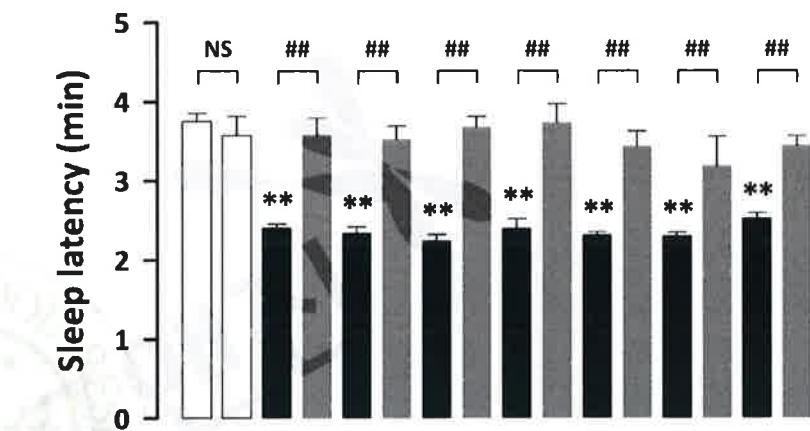
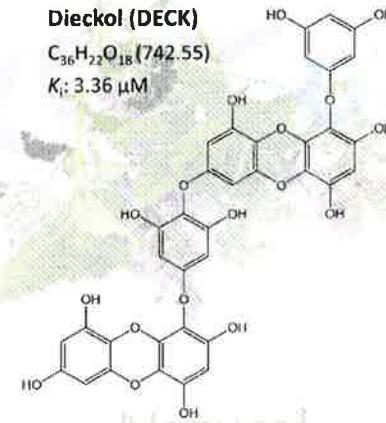


FIGURE 15.1 Possible hypnotic mechanism and metabolic route of polyphenols as a ligand of the gamma-aminobutyric acid type A-benzodiazepine (GABA_A-BZD) receptor.

Sub-chronic administration of PRT



Hypnotic effects of major constituents

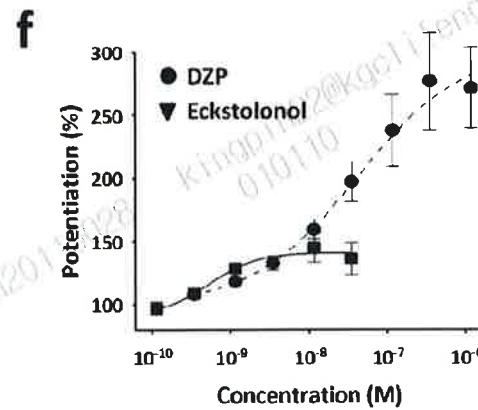
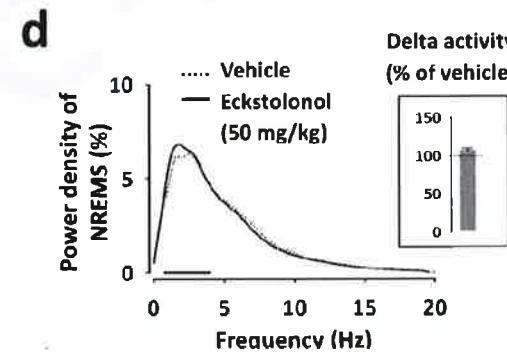
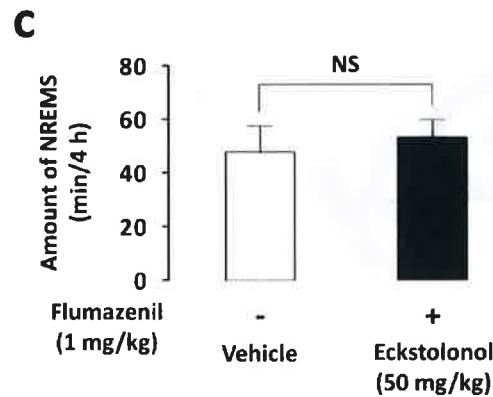
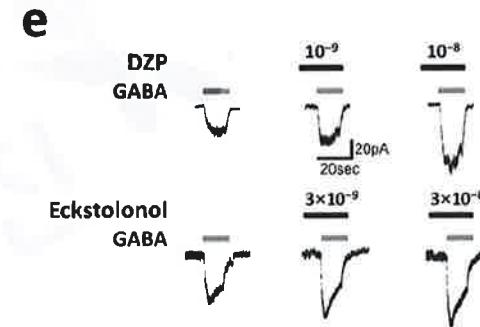
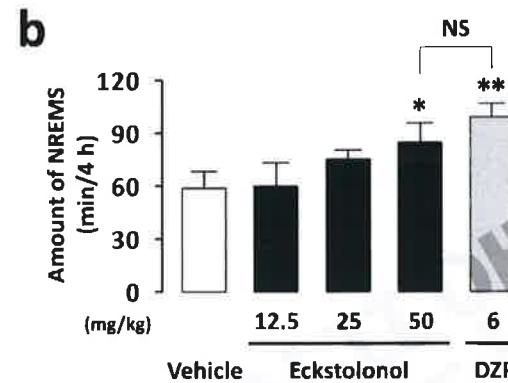
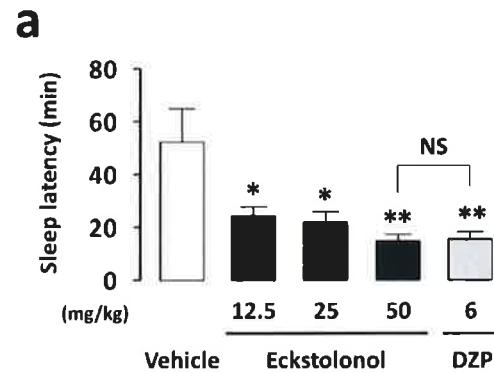
Eckstolonol (ETN) $C_{18}H_{10}O_9$ (370.27) K_i : 1.49 μM **Triphlorethol A (TPRA)** $C_{18}H_{14}O_9$ (374.30) K_i : 4.42 μM **Eckol (ECK)** $C_{18}H_{12}O_9$ (372.28) K_i : 1.07 μM **Fucodiphlorethol G (FDRG)** $C_{24}H_{18}O_{12}$ (498.39) K_i : 2.97 μM **6,6'-Bieckol (BECK)** $C_{36}H_{22}O_{18}$ (742.55) K_i : 3.07 μM **Dieckol (DECK)** $C_{36}H_{22}O_{18}$ (742.55) K_i : 3.36 μM 

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Sleep-promoting effects of eckstolonol



Pharmacophore model of eckstololonol

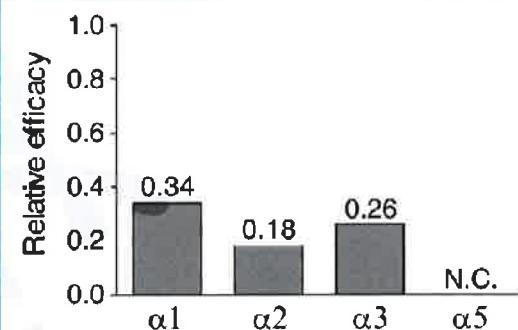
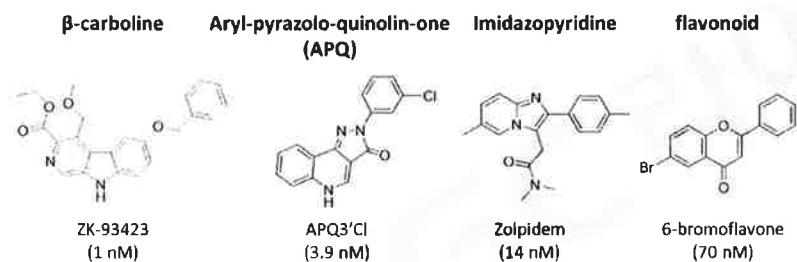
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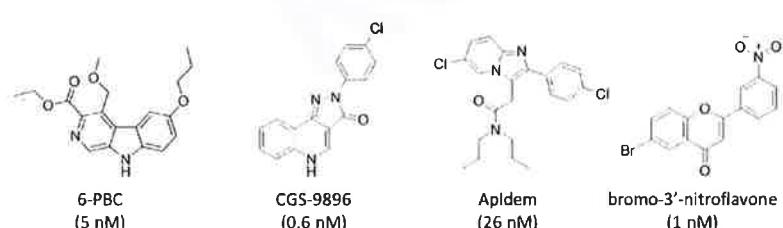
European Journal of Neuroscience, Vol. 29, pp. 1779–1794, 2009

doi:10.1111/j.1460-9568.2009.06716.x

REVIEW

Role of GABA_A receptors in the physiology and pharmacology of sleep**a**

Full agonists



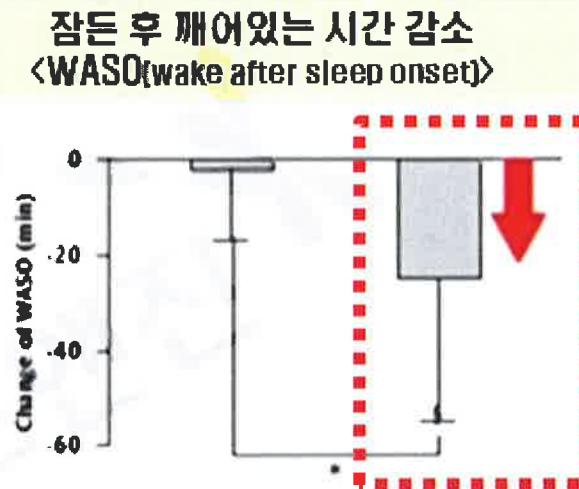
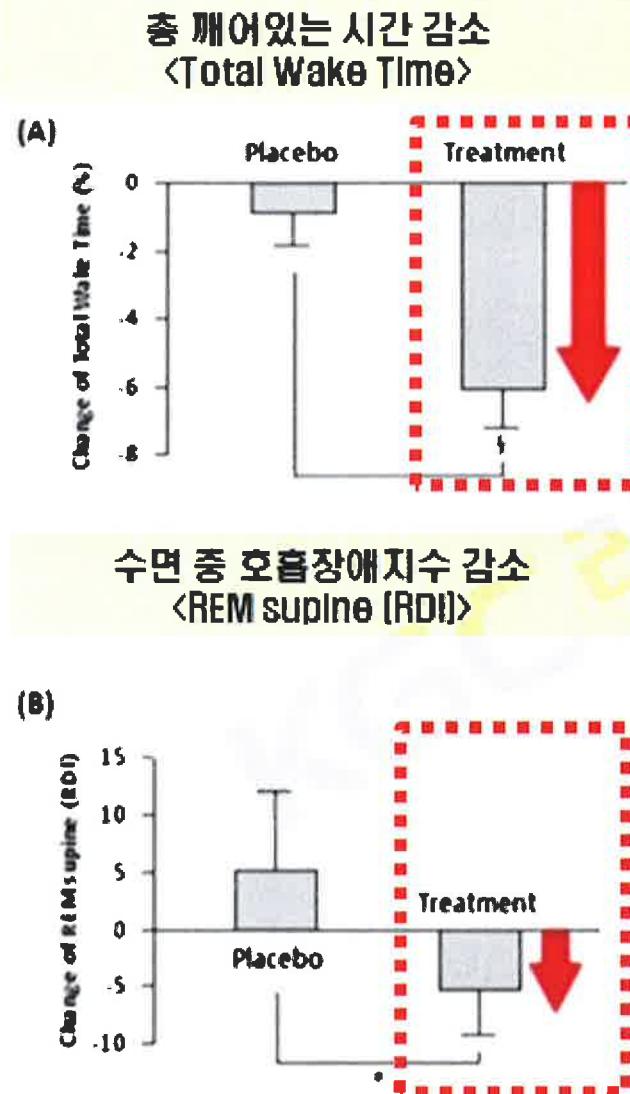
Partial agonists

b**c****d****e**



감태추출물의 수면개선 효과

(38/55)
2:27 PM



* 출처: 감태추출물 인체시험보고서

Figure 3. Change of (A) Total Wake Time, (B) REM supine(RDI), (C) WASO

§) Within group comparison, paired t-test, $P < 0.05$

*) Between groups comparison, independent t-test, $P < 0.05$

[가능성 인정내용]

수면의 질 개선에 도움
(생리활성 2등급)



감태, 국내 최초 수면개선 건강기능식품

(39/55)
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성과의 의의

- 국가기관인 식약처가 공식 인정해준 것으로 국내 식품산업의 이정표가 되는 매우 의미 있는 성과
- 수면 기능성은 개별인정 획득이 어렵다는 인식 속에서 각고의 노력으로 국내 최초 획득
- 국내 고유의 기술로 수면개선 건강기능식품 개발로 국내 식품분야 기술수준의 향상에 기여
- 수면개선 기능성의 신규 인정으로 국내 식품산업 신시장 창출을 통한 창조경제형 성과

인정 현황



[감태]

개별인정원료



식품의약품안전처
MINISTRY OF FOOD AND DRUG SAFETY

제 목 감태추출물

담당자 인정현황

등록일 2015.01.08

원재료 : 감태추출물(Ecklonia cava)

인정번호 : 기능성원료 인정 제2015-6호 (2015.01.08)

기능성 내용: 수면의 질 개선에 도움을 줄 수 있음 (생리활성 2등급)



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