

13 GIUGNO 2025

AULA MAGNA U. DINI
DELLA SCUOLA DI INGEGNERIA
DELL'UNIVERSITÀ DI PISA

LARGO LUCIO LAZZARINO
56122 PISA PI



STANDARDIZATION O BY-DESIGN: QUALI PROSPETTIVE PER L'HTA

TECHNOLOGY MANAGEMENT

14:50

Prof. Ugo Faraguna

Wearable devices: evoluzioni ed orizzonti

Ugo Faraguna, MD PhD

Professore Associato in Fisiologia Umana

Scuola di Medicina - Università di Pisa

IRCCS Fondazione Stella Maris



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STELLA MARIS



Gemini Flash 2.5

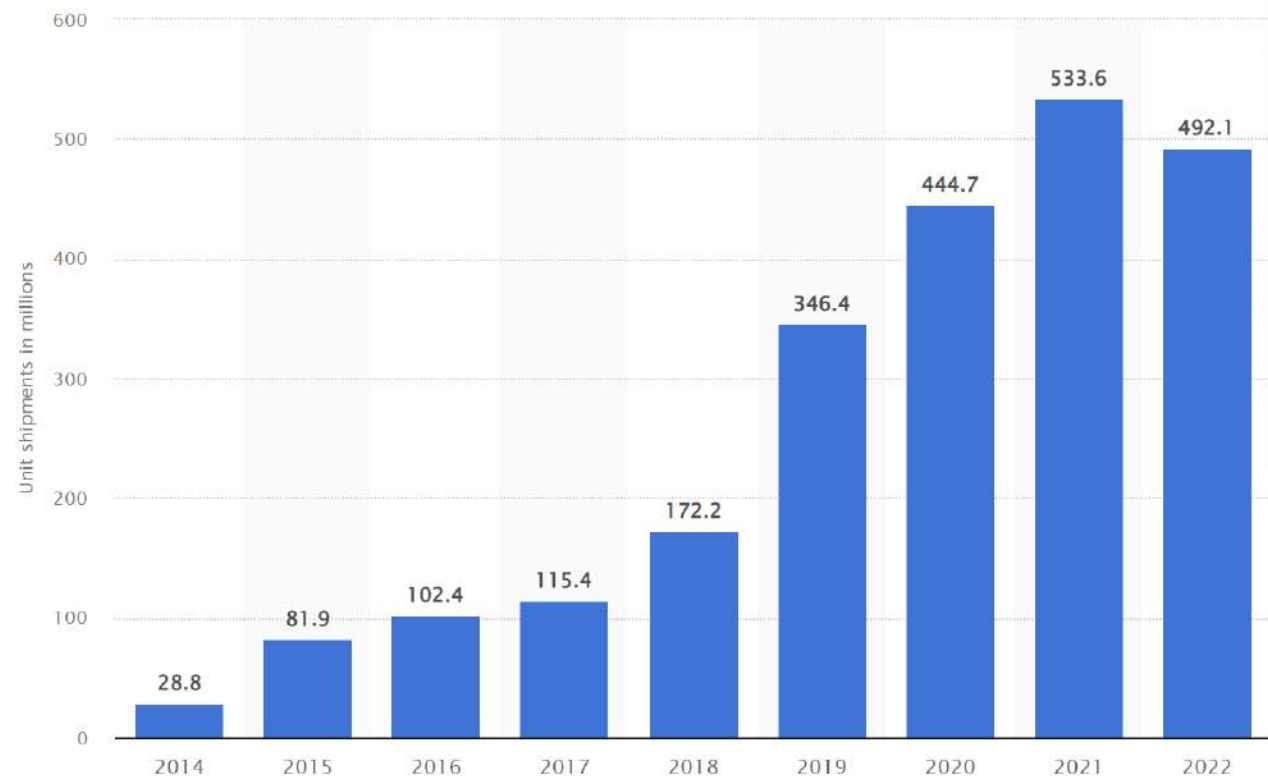
Generate a medical image for a seminar entitled
"wearable devices: evoluzione e orizzonti"

Potential Conflict of Interest

U.F. is President and Co-founder of Sleepacta s.r.l., a spinoff company of the University of Pisa operating in the field of non-invasive sleep detection based on machine-learning algorithms.

Wearables unit shipments worldwide from 2014 to 2022

(in millions)



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nature

Accelerated Article Preview



Automated loss of pulse detection on a consumer smartwatch

[Home](#) > [THE LATEST NEWS](#)

Received: 19 November 2024

Accepted: 19 February 2025

Accelerated Article Preview

Published online: 26 February 2025

Cite this article as: Shah, K. et al.
Automated loss of pulse detection
on a consumer smartwatch. *Nature*
<https://doi.org/10.1038/s41586-025-08810-9>
(2025)

By Edward Shi

Feb 26, 2025



Loss of Pulse Detection has received U.S. FDA clearance, and is now available on Pixel Watch 3.

Today, Google received clearance from the U.S. Food and Drug Administration (FDA) for our [Loss of Pulse Detection](#) feature starting with [Pixel Watch 3](#). This first-of-its-kind feature can detect when you've experienced a loss of pulse (your heart stops beating from an event like primary cardiac arrest, respiratory or circulatory failure, overdose or poisoning) and automatically prompt a call to emergency services for potentially life-saving care if you're unresponsive.



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STANDARDIZATION 0 BY-DESIGN:
QUALI PROSPETTIVE PER L'HTA



Fluid boundaries
between the world
of wellness and the
scientific/medical
world.

Copilot-generated 2025
Create a futuristic image of fluid boundaries between medical and
wellness depicting and arm wearing a smartwatch and a smart band

The first hands-free connected home urine lab



Wearables serve and will serve 5 P Medicine

- **Predictive:** Focusing on anticipating diseases before they manifest.
- **Preventive:** Aiming to take measures to avert illness.
- **Personalized:** Tailoring treatments and interventions to the individual.
- **Participatory:** Encouraging active involvement of the patient in their own care.
- **Population-based:** Considering the health of broader communities and populations.

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Monitorare il sonno con le nuove tecnologie

Un'opportunità per gli studi epidemiologici su vasta scala

ALL OF US UK BIOBANK



Immagine generata con Imagen3
Prompt: crea un'immagine per studi epidemiologici su vasta scala con wearable devices

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**STANDARDIZATION O BY-DESIGN:
QUALI PROSPETTIVE PER L'HTA**

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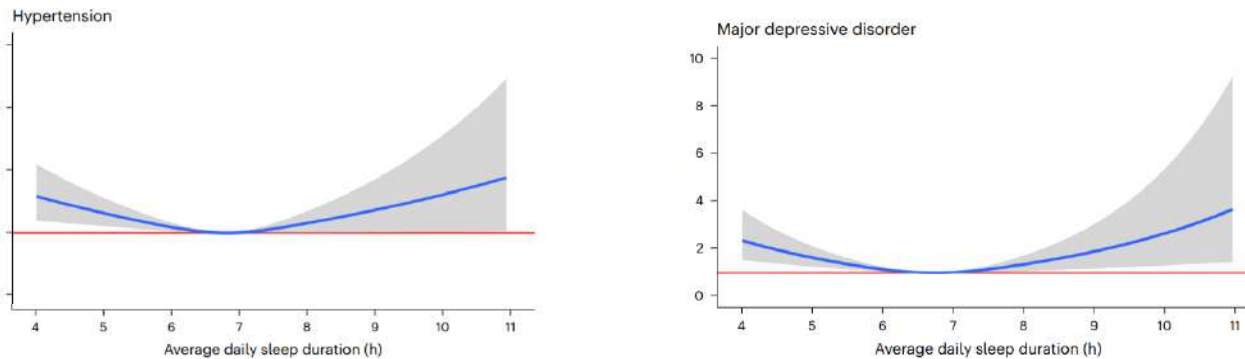
ManSan
Management delle Scienze Sanitarie

Sleep patterns and risk of chronic disease as measured by long-term monitoring with commercial wearable devices in the All of Us Research Program

Received: 27 December 2023

A list of authors and their affiliations appears at the end of the paper

Accepted: 25 June 2024



6,785 participants included in this study

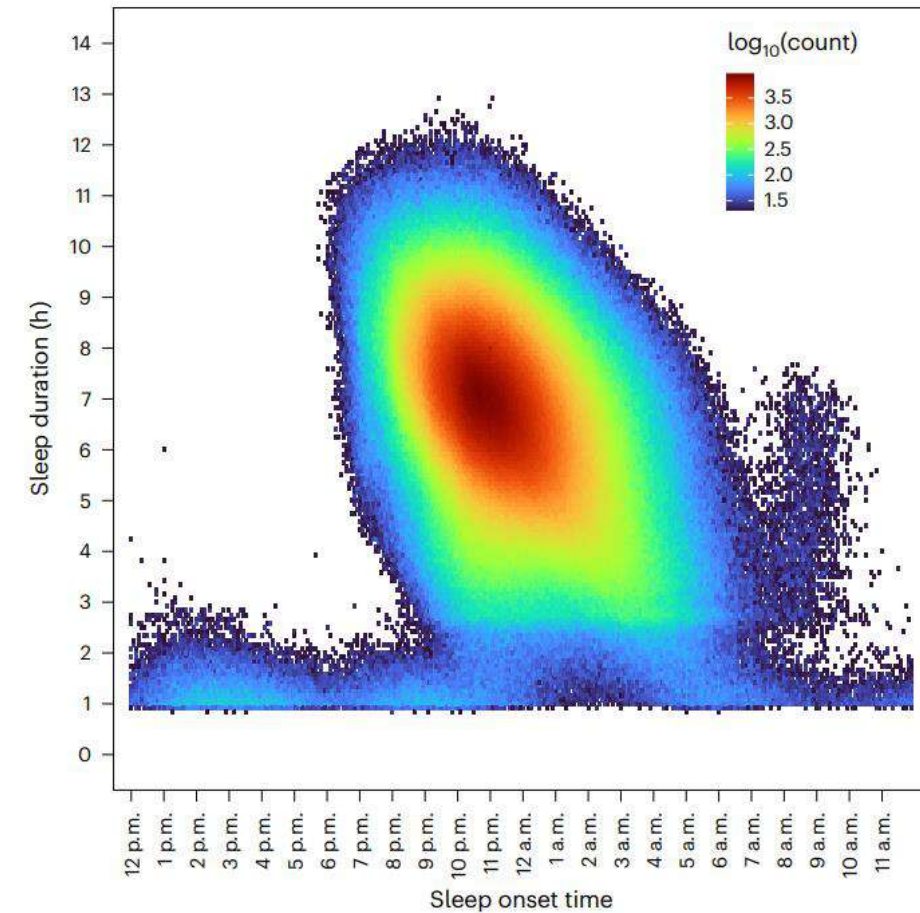


Fig. 1 | Heatmap of sleep onset time and total sleep duration for all person-nights. Heatmap of sleep duration is plotted versus sleep onset time across all person-nights. All sleep periods were flagged as 'main sleep' by Fitbit devices.

Diurnal rhythms of wrist temperature are associated with future disease risk in the UK Biobank

Received: 7 February 2023

Accepted: 15 August 2023

Published online: 24 August 2023

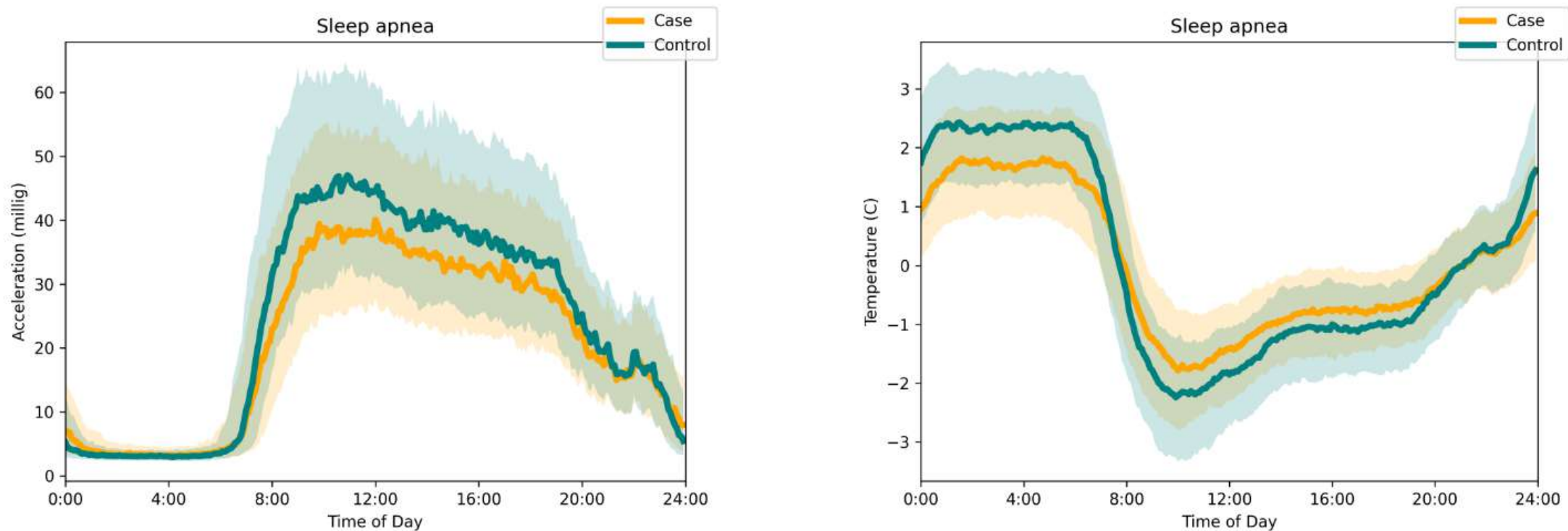
 Check for updatesThomas G. Brooks¹ , Nicholas F. Lahens¹, Gregory R. Grant^{1,2},
Yvette I. Sheline^{3,4,5} , Garret A. FitzGerald^{1,6,7} & Carsten Skarke^{1,6} 

Many chronic disease symptomatology involves desynchronized sleep-wake cycles, indicative of disrupted biorhythms. This can be interrogated using body temperature rhythms, which have circadian as well as sleep-wake behavior/environmental evoked components. Here, we investigated the association of wrist temperature amplitudes with a future onset of disease in the UK Biobank one year after actigraphy. Among 425 disease conditions (range $n = 200$ –6728) compared to controls (range $n = 62$,107–91,134), a total of 73 (17%) disease phenotypes were significantly associated with decreased amplitudes of wrist temperature (Benjamini-Hochberg FDR $q < 0.05$) and 26 (6.1%) PheCODEs passed a more stringent significance level (Bonferroni-correction $\alpha < 0.05$). A two-standard deviation (1.8° Celsius) lower wrist temperature amplitude corresponded to hazard ratios of 1.91 (1.58–2.31 95% CI) for NAFLD, 1.69 (1.53–1.88) for type 2 diabetes, 1.25 (1.14–1.37) for renal failure, 1.23 (1.17–1.3) for hypertension, and 1.22 (1.11–1.33) for pneumonia (phenome-wide atlas available at http://bioinf.itmat.upenn.edu/biorhythm_atlas/). This work suggests peripheral thermoregulation as a digital biomarker.



Acceleration and Temperature traces

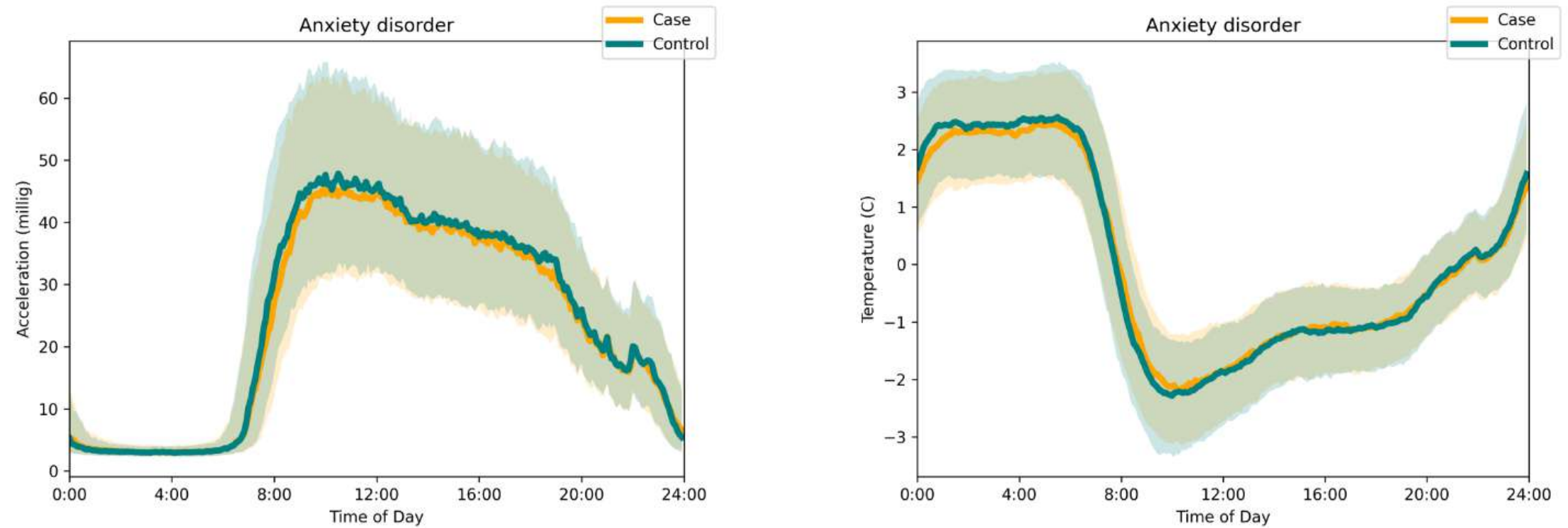
Acceleration and wrist temperature were measured using an wrist-worn Axivity AX3 for one-week periods ([Doherty, et al 2017](#)). Below are the average acceleration and wrist temperature values by case/control status across the day.



Generated from 745 case-controls pairs, matched by age and sex. Temperature values are normalized to have median 0 in each individual. Solid curves give median value for the population at that time of day, and shaded regions indicate the middle 50% of the population.

Acceleration and Temperature traces

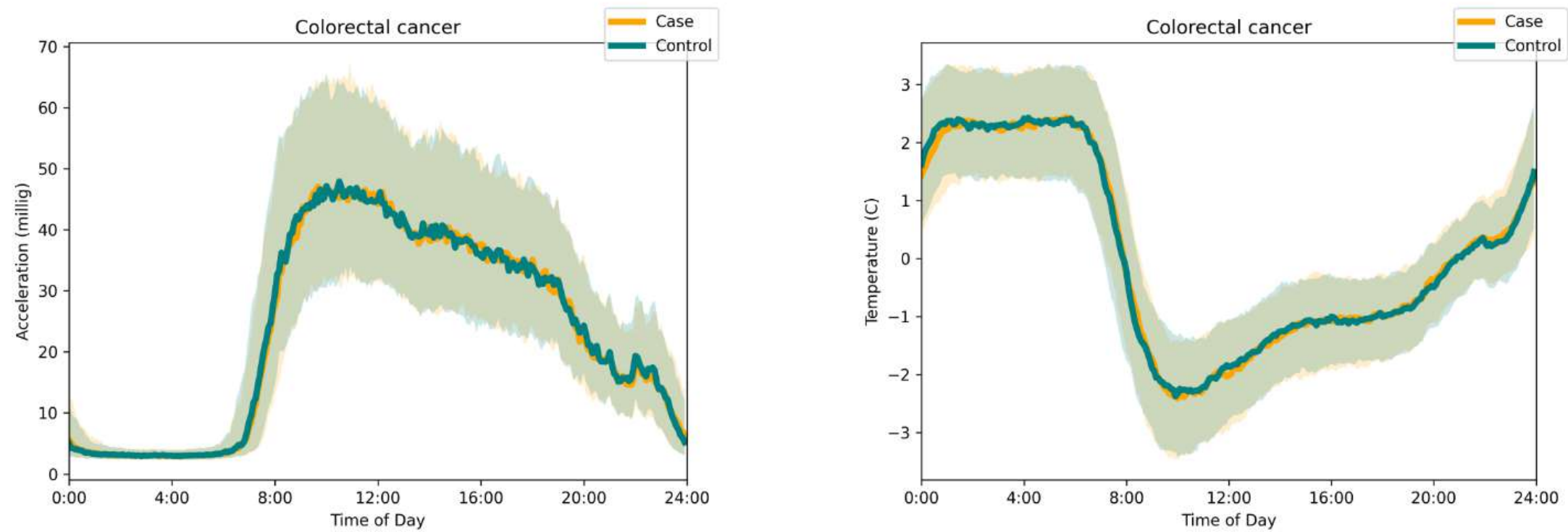
Acceleration and wrist temperature were measured using an wrist-worn Axivity AX3 for one-week periods ([Doherty, et al 2017](#)). Below are the average acceleration and wrist temperature values by case/control status across the day.



Generated from 1500 case-controls pairs, matched by age and sex. Temperature values are normalized to have median 0 in each individual. Solid curves give median value for the population at that time of day, and shaded regions indicate the middle 50% of the population.

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Il dato grezzo della temperatura distale

nature communications

Article

<https://doi.org/10.1038/s41467-023-40977-5>

Diurnal rhythms of wrist temperature are associated with future disease risk in the UK Biobank

Received: 7 February 2023

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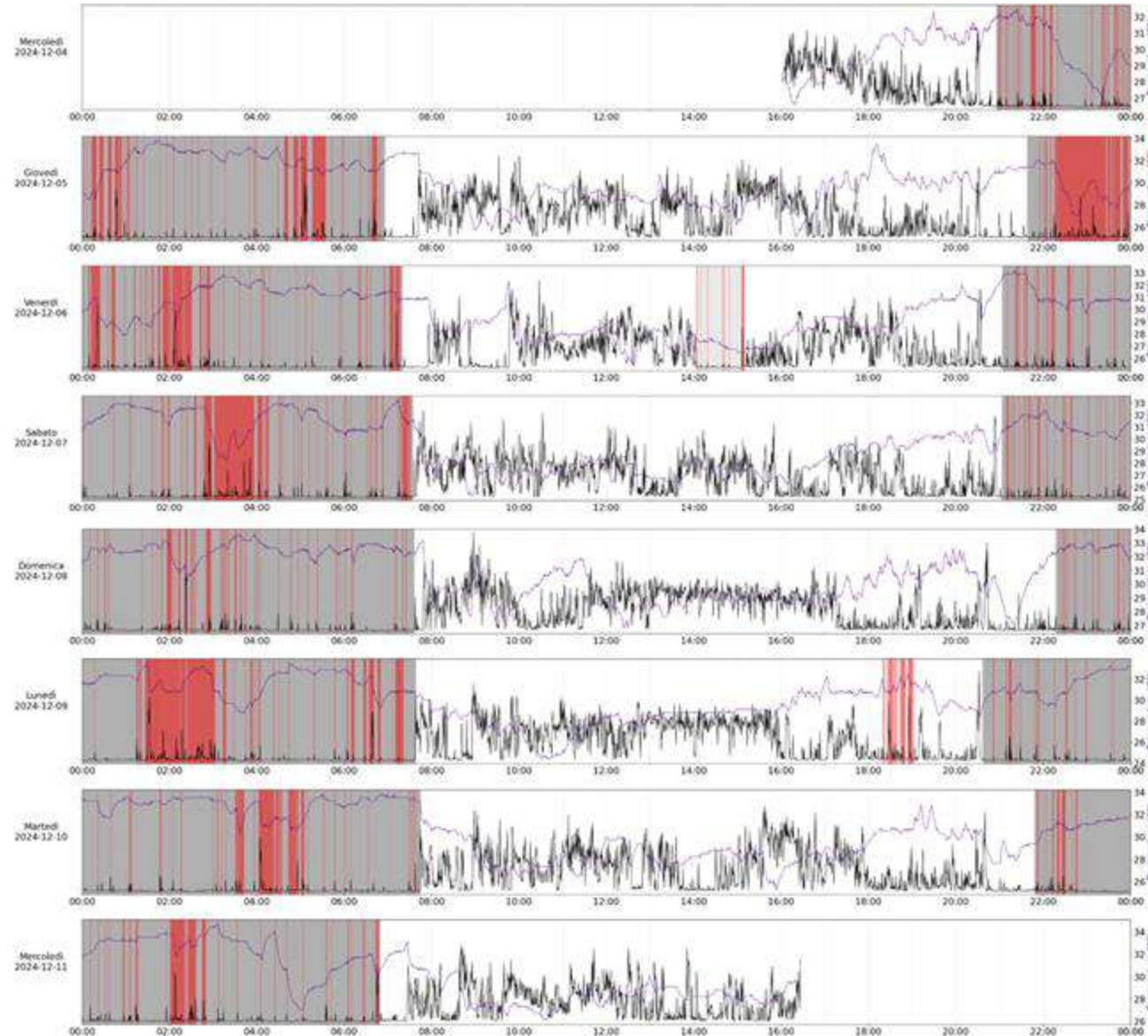
Yvette I. Sheline^{3,4,5}, Garret A. Fitzgerald^{1,6,7} & Carsten Skarke^{1,6}

RILEVAMENTO DEGLI EPISODI DI SONNO:

- **sonno:** sfondo grigio
- **nap (sonno diurno):** sfondo grigio chiaro
- **risvegli:** rosso su sfondo grigio

TRACCIATO ACTIGRAFICO:

- **movimento:** linea nera sottile
- **temperatura al polso:** linea viola sottile



Il dato grezzo della temperatura distale

RILEVAMENTO DEGLI EPISODI DI SONNO:

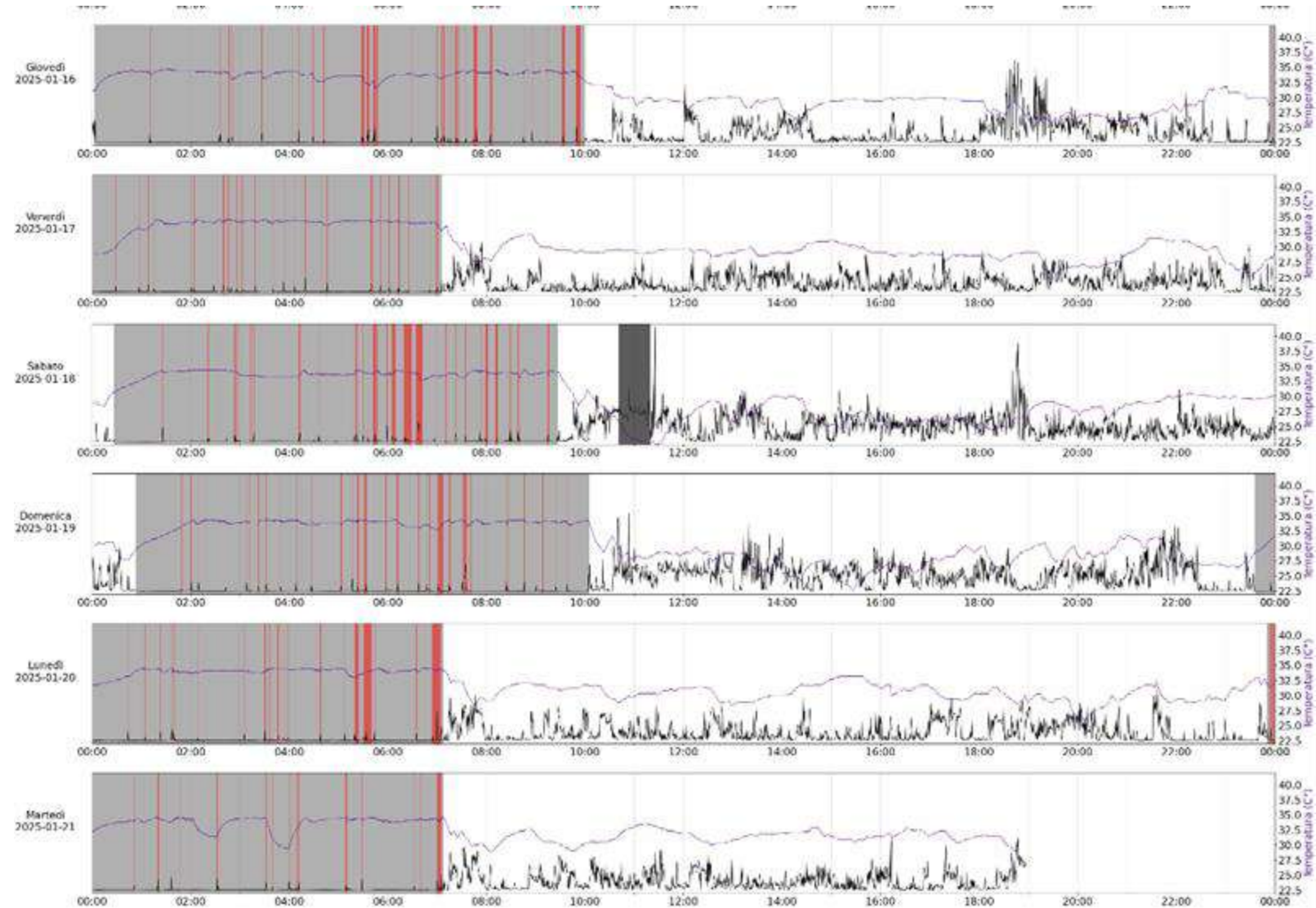
- **sonno:** sfondo grigio
- **nap (sonno diurno):** sfondo grigio chiaro
- **risvegli:** rosso su sfondo grigio

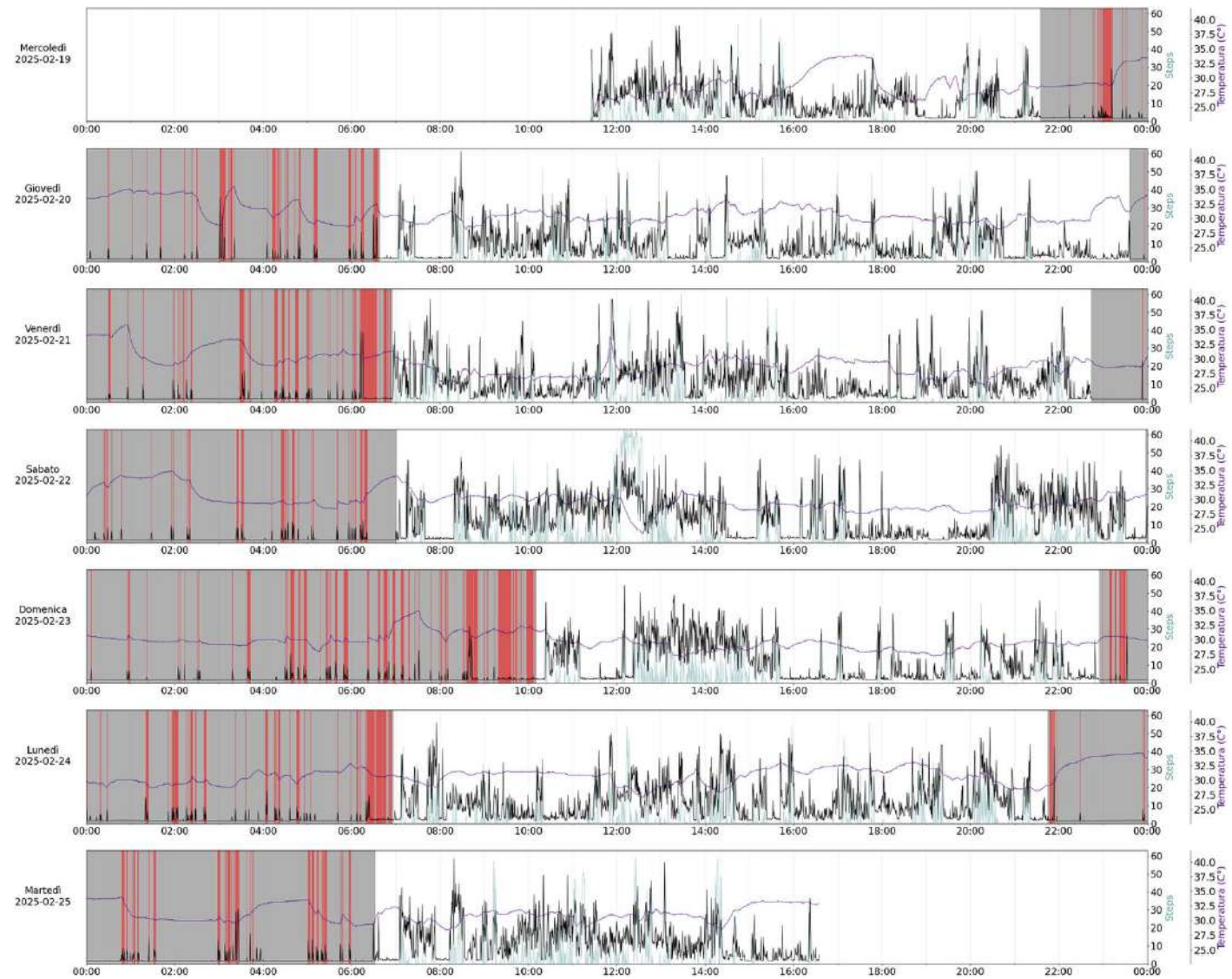
TRACCIATO ACTIGRAFICO:

- **movimento:** linea nera sottile
- **temperatura al polso:** linea viola sottile

NO WEAR TIME

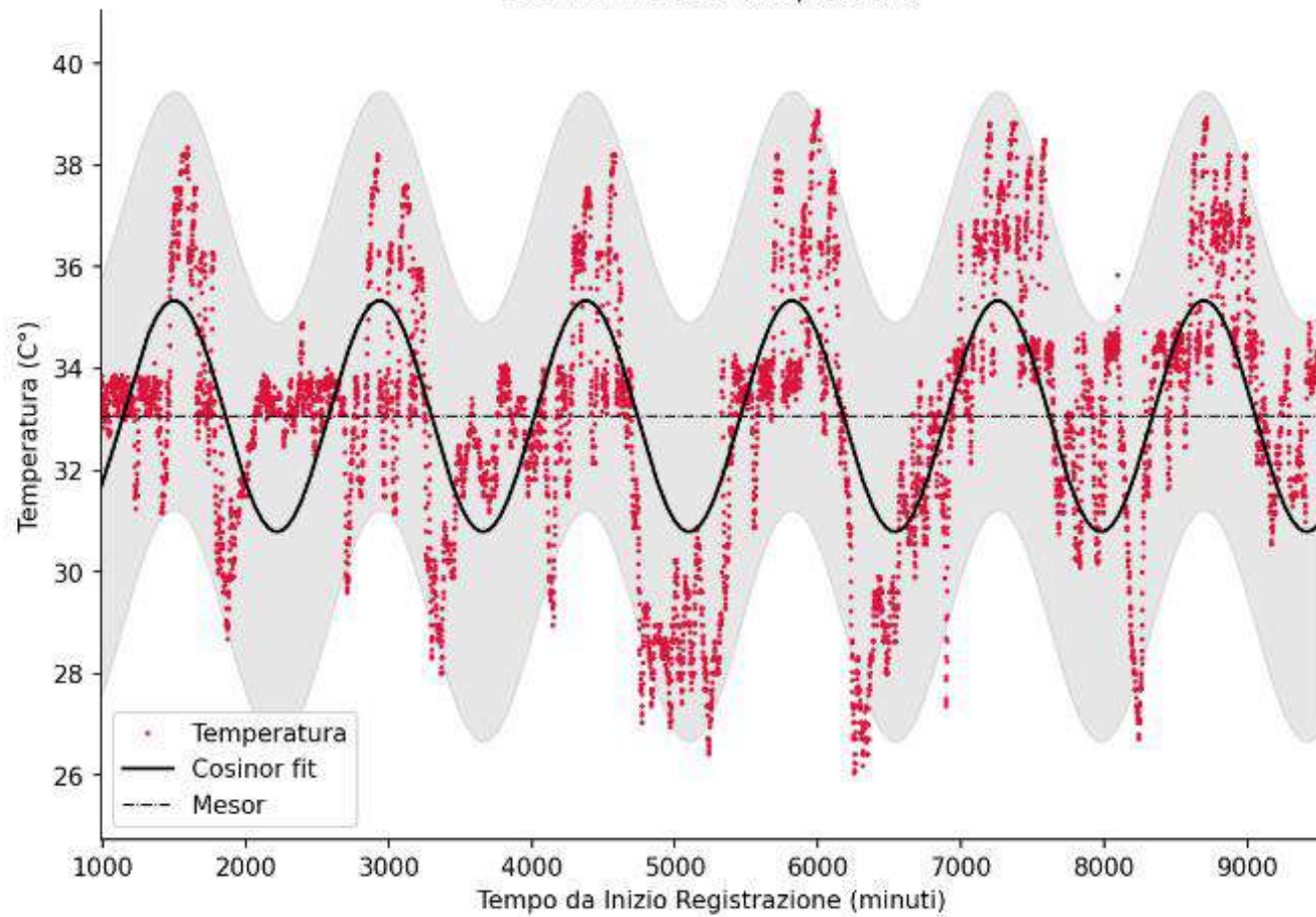
Il soggetto ho tolto il dispositivo: grigio scuro



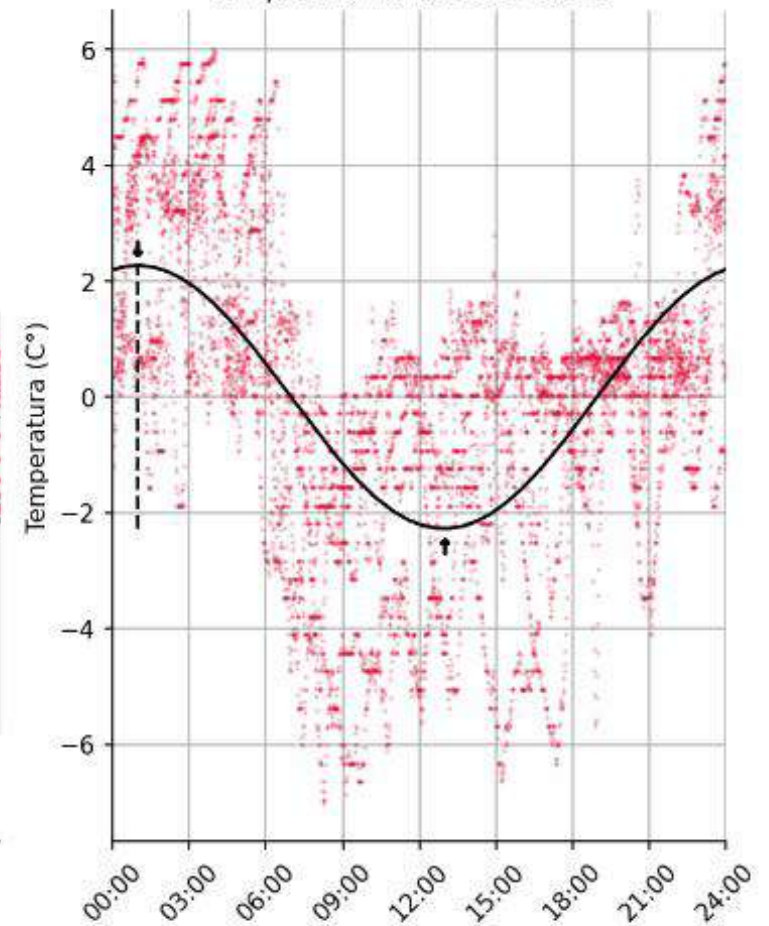


Andamento Temperatura del Dispositivo

Cosinor Fit Dati Temperatura

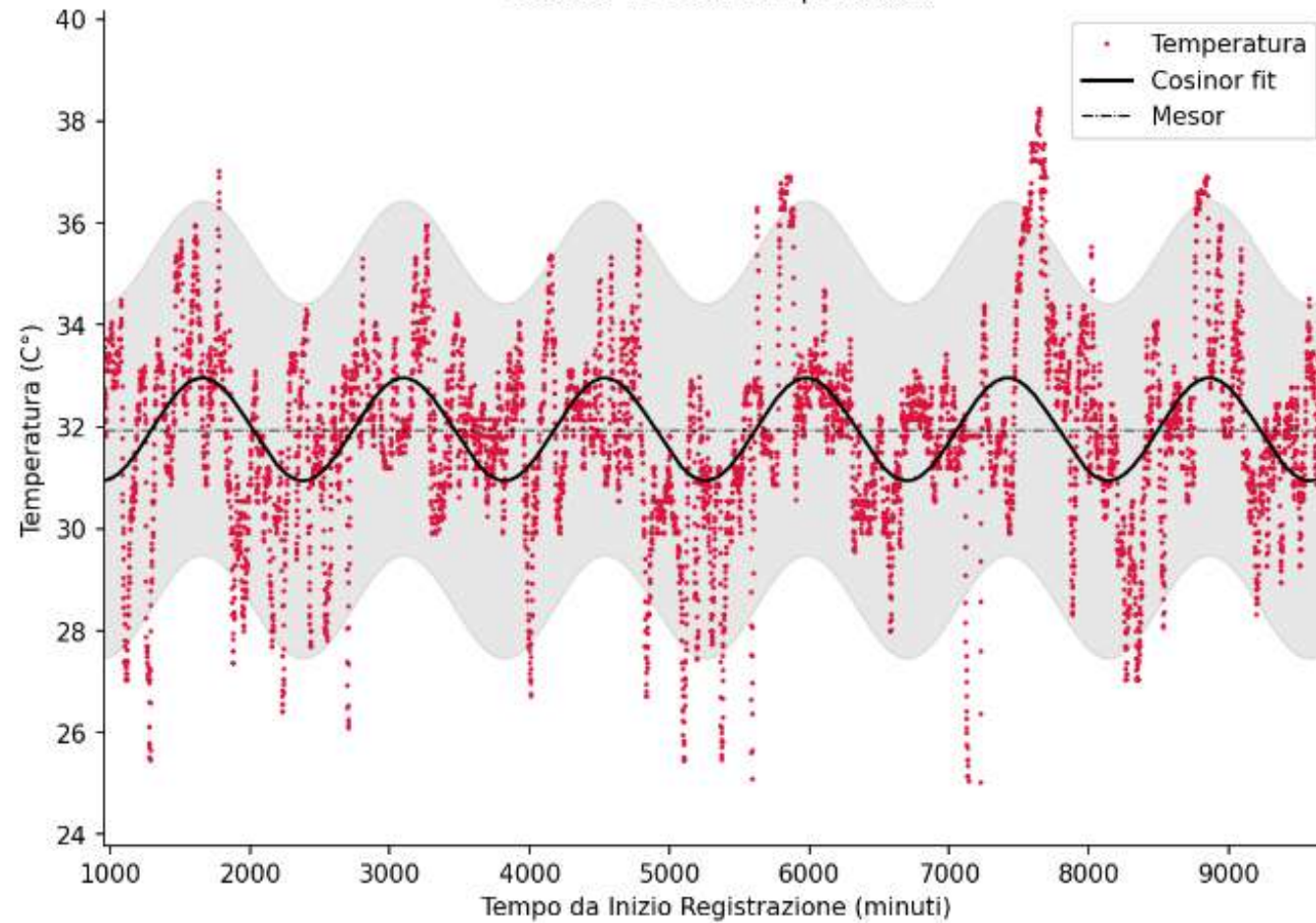


Ampiezza Variazione 2.3 C°

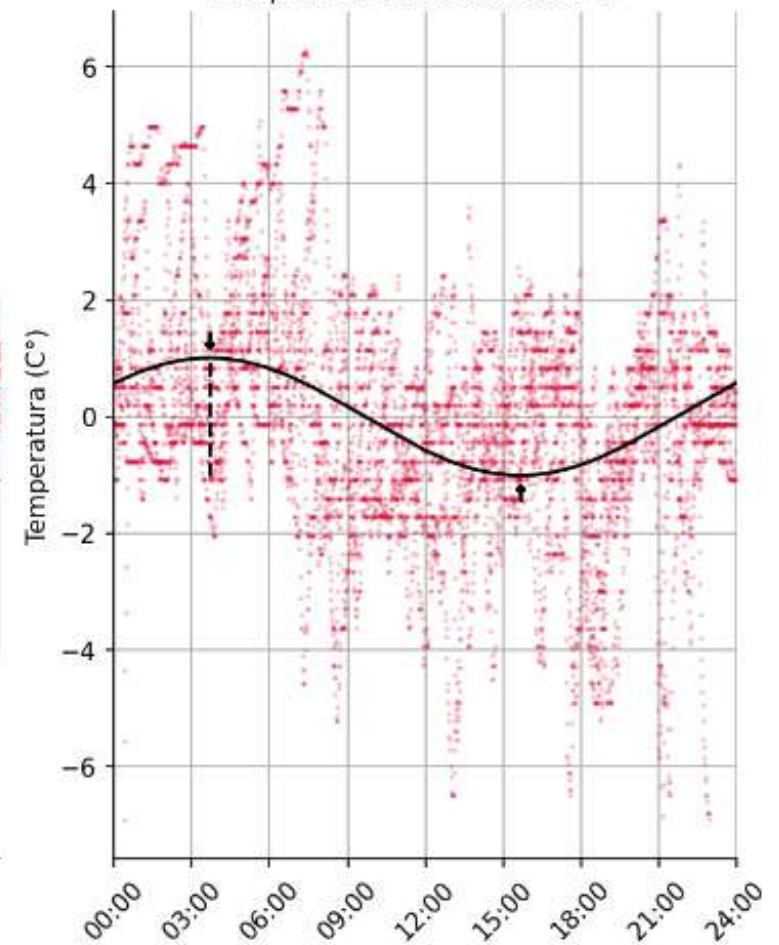


Andamento Temperatura del Dispositivo

Cosinor Fit Dati Temperatura



Ampiezza Variazione 1.0 C°



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REVIEW

Optimizing the Time and Dose of Melatonin as a Sleep-Promoting Drug: A Systematic Review of Randomized Controlled Trials and Dose–Response Meta-Analysis

Francy Cruz-Sanabria¹  | Simone Bruno²  | Alessio Crippa³  | Paolo Frumento⁴  | Marco Scarselli²  | Debra J. Skene⁵  | Ugo Faraguna^{1,2} 

¹Department of Developmental Neuroscience, Istituto di Ricovero e Cura a Carattere Scientifico (IRCCS) Fondazione Stella Maris, Pisa, Italy | ²Department of Translational Research and of New Surgical and Medical Technologies, University of Pisa, Pisa, Italy | ³Department of Public Health Sciences, Karolinska Institutet, Stockholm, Sweden | ⁴Department of Political Sciences, University of Pisa, Pisa, Italy | ⁵Chronobiology, Faculty of Health and Medical Sciences, University of Surrey, Guildford, UK

Correspondence: Francy Cruz-Sanabria (francy.cruzsanabria@phd.unipi.it; francycruz17@gmail.com) | Ugo Faraguna (ugo.faraguna@unipi.it)

Received: 25 May 2023 | **Revised:** 3 January 2024 | **Accepted:** 30 May 2024

Keywords: dose–response relationship | drug administration schedule | hypnotics and sedatives | melatonin | sleep initiation and maintenance disorders | sleep wake disorders | time factors

Insonnia, ecco quanta melatonina conviene assumere

Una ricerca dell'Università di Pisa ha rilevato che la melatonina è più efficace se assunta tre ore prima di coricarsi, con una dose di 4 mg al giorno

di Redazione
03.07.2024

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Melatonina: quando prenderla e in che dose perché funzioni contro l'insonnia

Uno studio dell'Università di Pisa indica la modalità migliore di assumere questo ormone per favorire il sonno



DI SIMONE COSIMI

22 GIUGNO 2024

13 GIUGNO 2025

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TABLE 4 | Meta-regression model was estimated considering the standardized mean difference in sleep onset latency (melatonin—placebo) as the dependent variable and the time window between exo-MEL administration and the sleep episode as a predictor.

	Estimate	Standard error	p value
Intercept	−0.24	0.12	0.04*
0			
1	−0.14	0.25	0.57
2	−0.44	0.17	0.01*
3	−0.60	0.28	0.01*

Note: Administration time was included in the model as a categorical variable expressing the number of hours at which exo-MEL was taken with respect to the sleep episode. For the categorization procedure, please refer to the Section 2. Bedtime (i.e., 0 h before the sleep episode) was considered as the reference for comparison and represented in the Table by a blank row. Administering exo-MEL 1 h before the sleep episode did not significantly improve its efficacy as compared to the administration right before the sleep episode, whereas both 2 and 3 h before the sleep episode were associated with a significant reduction in sleep onset latency. Of note, the effect size is higher for 3 h before the sleep episode as compared to 2 h ($\beta = -0.60$ vs. $\beta = -0.46$, respectively). Significance code: * $p < 0.05$.



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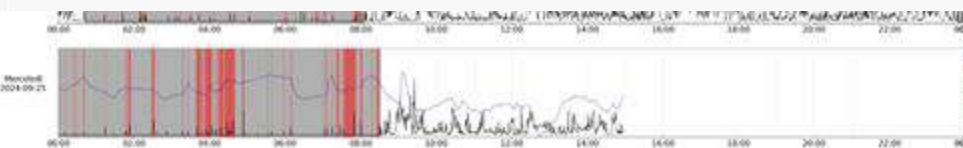
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Orario desiderato di addormentamento	Orario suggerito di somministrazione, a stomaco pieno	Orario suggerito di somministrazione, a digiuno
20:00	Arrivare alle 17:00 gradualmente, iniziando dalle 18:46 (fine copertura alle 03:00)	Posologia non applicabile
21:00	Arrivare alle 18:00 gradualmente, iniziando dalle 18:46 (fine copertura alle 04:00)	Posologia non applicabile
22:00	Arrivare alle 19:00 gradualmente, iniziando dalle 18:46 (fine copertura alle 05:00)	Arrivare alle 21:15 gradualmente, iniziando dalle 21:01 (fine copertura alle 02:45)
23:00	Arrivare alle 20:00 gradualmente, iniziando dalle 18:46 (fine copertura alle 06:00)	Arrivare alle 22:15 gradualmente, iniziando dalle 21:01 (fine copertura alle 03:45)
00:00	Arrivare alle 21:00 gradualmente, iniziando dalle 18:46 (fine copertura alle 07:00)	Arrivare alle 23:15 gradualmente, iniziando dalle 21:01 (fine copertura alle 04:45)
01:00	Arrivare alle 22:00 gradualmente, iniziando dalle 18:46 (fine copertura alle 08:00)	Arrivare alle 00:15 gradualmente, iniziando dalle 21:01 (fine copertura alle 05:45)



21:43	21:27	21:16	21:57	22:18	22:09	21:40	21:29	21:29
2024-09-17	2024-09-18	2024-09-19	2024-09-20	2024-09-21	2024-09-22	2024-09-23	2024-09-24	2024-09-25

— Sonno — ENMO — SSA Comp. Circadiana — Cosinor — Stima DLMO
- - - Fase Circadiana



CONCLUSIONI

Wearable Devices: Evoluzioni ed Orizzonti

- La tecnologia indossabile sta colmando il divario tra il benessere e le applicazioni mediche, aprendo nuove possibilità per il monitoraggio e l'intervento sulla salute.
- Il mercato dei dispositivi indossabili ha registrato una crescita significativa, con centinaia di milioni di unità spedite in tutto il mondo ogni anno.
- Algoritmi avanzati, incluso il machine learning, stanno migliorando le capacità dei dispositivi indossabili per il rilevamento non invasivo della salute, come l'analisi del sonno.
- I dispositivi indossabili si stanno dimostrando preziosi per studi epidemiologici su larga scala, consentendo il monitoraggio a lungo termine di vari parametri di salute e la loro associazione con malattie croniche.
- Un orizzonte promettente è l'utilizzo dei wearable per lo screening precoce e continuo di diverse condizioni, facilitando interventi tempestivi.
- Le prospettive future includono una maggiore integrazione di questi dispositivi nella vita quotidiana per ottenere continue informazioni sulla salute e la diagnosi precoce di condizioni, portando potenzialmente a un approccio sanitario più personalizzato e preventivo.

David	Anguillesi
Simone	Antonelli
Tommaso	Banfi
Cristiana	Barghini
Andrea	Bazzani
Marco	Bendinelli
Davide	Benedetti
Francesca	Bettosini Giusti
Enrica	Bonanni
Eleni	Chioutakou
Gastone	Ciuti
Alessandro	Colitta
Tutti	Colorochehodimenticato
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Grazie