

Interpreting the Relationship Among Itch, Sleep, and Work Productivity in Patients with Moderate-to-Severe Atopic Dermatitis: A Post Hoc Analysis of JADE MONO-2

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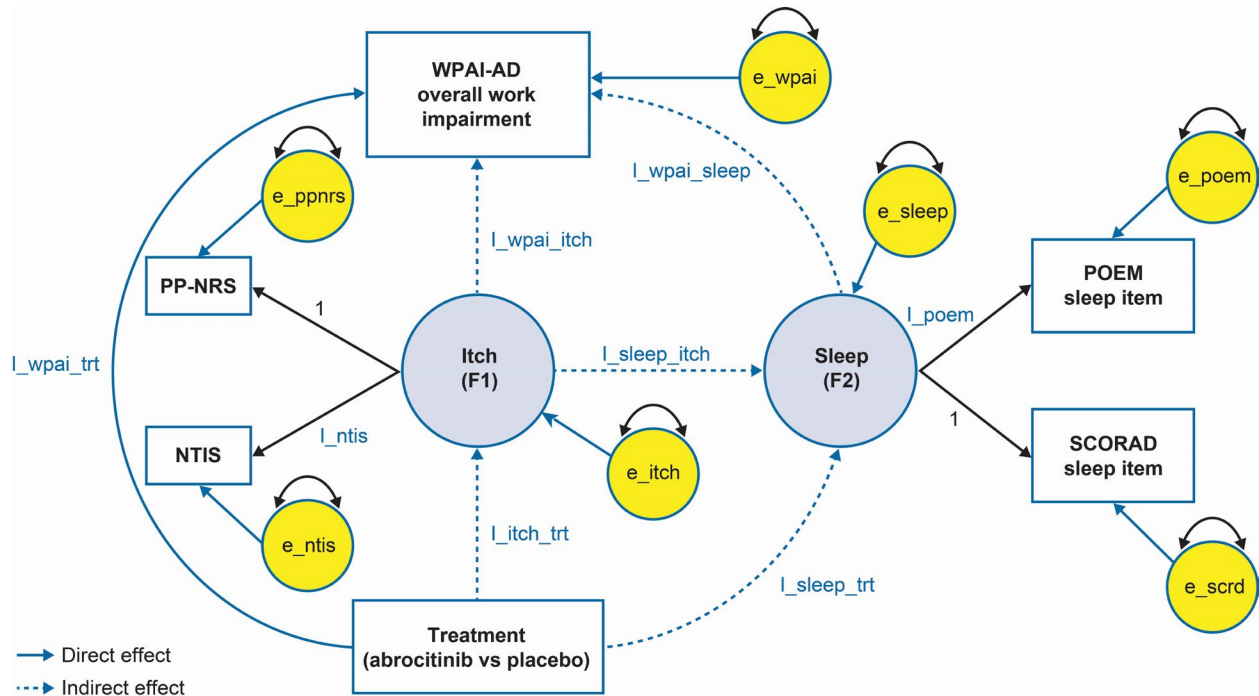
Conflict of Interest

Gil Yosipovitch is a consultant and advisor for Cara Therapeutics, Eli Lilly, Escient, Galderma, GlaxoSmithKline, Kiniksa, LEO Pharma, Novartis, Pfizer Inc., Regeneron, Sanofi, Trevi Therapeutics, and Vifor and a principal investigator for Arcutis, Celldex, Eli Lilly, Escient, Galderma, Kiniksa, LEO Pharma, Novartis, Pfizer Inc., and Sanofi Regeneron. Melinda J. Gooderham has received grants, personal fees, honoraria, and/or nonfinancial support from AbbVie, Amgen, AkrosPharma, AnaptysBio, Arcutis, ASLAN Pharmaceuticals, Bausch Health (Valeant), Bristol Myers Squibb, Boehringer-Ingelheim, Celgene, Dermavant Sciences, Dermira, Eli Lilly, Galderma, Janssen, Kyowa Kirin, LEO Pharma, MedImmune, Meiji, Merck, Novartis, Pfizer Inc., Roche, Sanofi Genzyme, Regeneron, Sun Pharma, and UCB. Sonja Ständer is a principal investigator for Almirall, Dermasence, Galderma, Kiniksa, LEO Pharma, Menlo

Therapeutics, Novartis, Sanofi, and Trevi Therapeutics; a member of scientific advisory boards for Beiersdorf, Celgene, Galderma, Kiniksa, Pfizer, and Trevi Therapeutics; and a consultant for Bellus Health, Galderma, Novartis, Sanofi, and Vifor. Luz Fonacier received research grants (made to NYU Langone Hospital-LI) from AstraZeneca, Pfizer, Regeneron, and Shire and was a consultant and advisor for AbbVie, Eli Lilly, Pfizer, and Regeneron. Jacek C. Szepietowski has been a consultant/advisory board member for LEO Pharma, Novartis, Sanofi-Genzyme, Trevi, and Viofor; a speaker for AbbVie, LEO Pharma, Novartis, Sanofi-Genzyme, and Sunfarm; and an investigator for AbbVie, Bristol Myers Squibb, Galapagos, Galderma, Helm, Incyte, InfaRX, Janssen-Cilag, Novartis, Pfizer, Regeneron, UCB, and Trevi. Mette Deleuran has been a principal investigator in clinical trials and an advisory board member and/or speaker for AbbVie, ASLAN, Arena Pharmaceuticals, Eli Lilly, Incyte, La Roche Posay, LEO Pharma, Novartis, Pfizer, Pierre Fabre, Regeneron, and Sanofi-Genzyme. Giampiero Girolomoni has been principal investigator in clinical trials sponsored by and/or has received personal fees from AbbVie, Almirall, Amgen, Biogen, Boehringer-Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly, Fresenius Kabi, Genzyme, LEO Pharma, Menlo Therapeutics, Novartis, OM Pharma, Pfizer, Regeneron, Samsung Bioepis, and Sanofi. John Su has received grants/research funding for his role as an investigator for AbbVie, Amgen, AstraZeneca, Bristol Myers Squibb, Eli Lilly, Galderma, Janssen, Novartis, Pfizer Inc., Pierre Fabre, and Sanofi; has received honoraria for serving on advisory boards for Eli Lilly, GSK, Janssen, LEO Pharma, L'Oréal, Novartis, Pfizer Inc., and Sanofi; and has received honoraria for serving as a speaker for Ego Pharmaceuticals and Pierre Fabre. Andrew G. Bushmakin, Pinaki Biswas, Claire Feeney, Hernan Valdez, Andrew J. Thorpe, Gary Chan, Joseph C. Cappelleri, Marco DiBonaventura, and Daniela E. Myers are employees and shareholders of Pfizer Inc. Ricardo Rojo is a former employee and current shareholder of Pfizer Inc.

SUPPLEMENTARY MATERIAL

Supplementary Fig S1 Initial mediation model



NTIS, Night Time Itch Scale; POEM, Patient-Oriented Eczema Scale; PP-NRS, Peak Pruritus Numerical Rating Scale; SCORAD, SCORing AD Sleep Loss Visual Analog Scale; WPAI-AD, Work Productivity and Activity Impairment – Atopic Dermatitis questionnaire version 2.0

Variable Treatment – "Abro" (value of 1) vs "Placebo" (value of 0)

Latent variable F1 represents itch (PP-NRS and NTIS). POEM sleep item and SCORAD sleep items represent latent sleep factor 2 (F2; measured at week 12)

Variables e_ppnrs, e_ntis, e_poem, e_scrd, e_wpai represent error terms

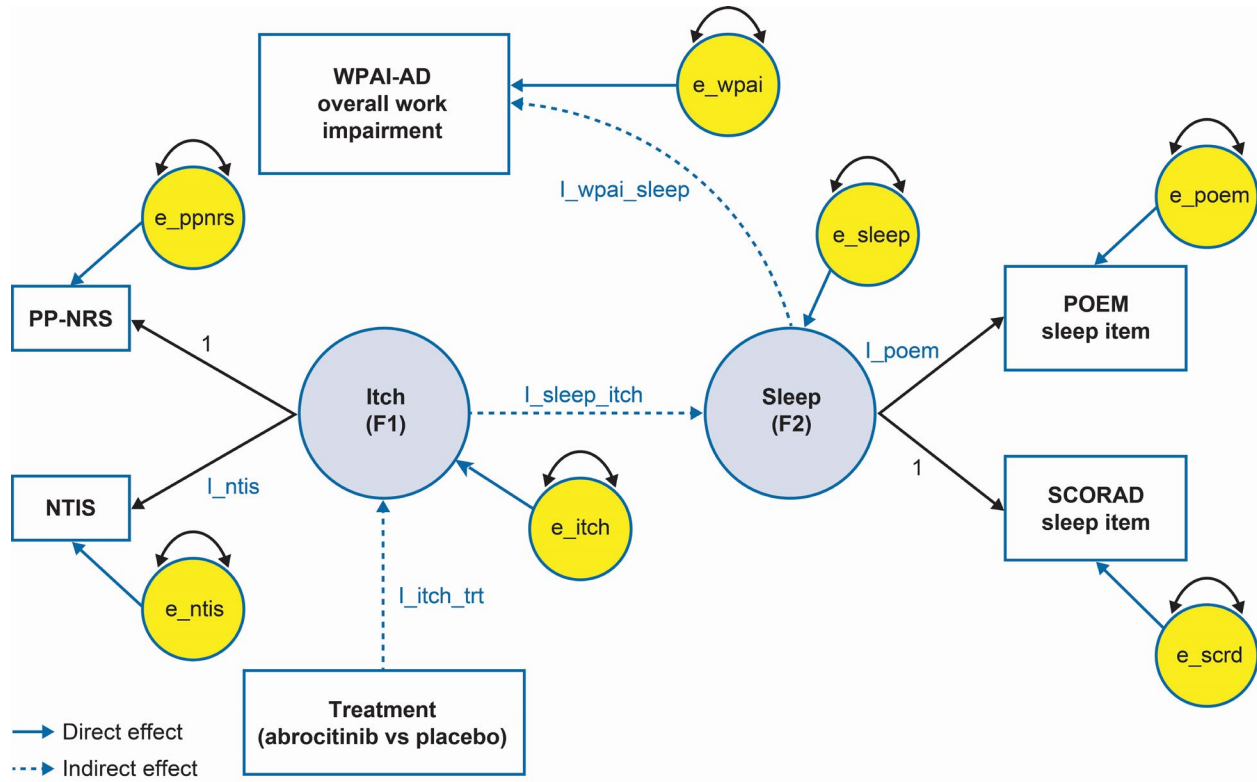
Variables e_itch, e_sleep represent disturbance terms

A curved two-headed arrow pointing to the same variable represents variance

Solid, single headed arrows, indicate direct paths

Dashed, single headed arrows, indicate indirect paths

Supplementary Fig S2 Re-specified mediation modeling



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