

Assessing the Relationship Between Pruritus and Work Productivity Among Individuals With PBC and Pruritus: Results From the ITCH-E Study

Cynthia Levy¹, Maria Agapova², Marvin Rock², Woodie Zachry², Chong Kim²

¹Schiff Center for Liver Diseases, University of Miami, Miami, FL, USA; ²Gilead Sciences, Inc., Foster City, CA, USA



Copies of this poster obtained through QR (Quick Response) and/or text key codes are for personal use only and may not be reproduced without written permission of the authors.

Conclusions

- Results from this analysis of the ITCH-E study suggest that pruritus severity is associated with lost work hours among employed adults with primary biliary cholangitis (PBC), emphasizing the need for safe and efficacious PBC treatments that can reduce pruritus
 - Further research is needed to understand whether other potential barriers to work productivity may exist among people with PBC
- ## Plain Language Summary
- People with primary biliary cholangitis (PBC) may experience itching as a symptom
 - This itching can be severe and cause problems with sleep, tiredness, and pain
 - This study looked at whether itching affects people’s ability to do work
 - The study results suggested that people with more severe itch lost more hours of work than those with less severe itch
 - Medicines that effectively reduce itch are needed to address this problem

References: 1. European Association for the Study of the Liver. *J Hepatol.* 2017;67(1):145-72. 2. Onofrio FQ, et al. *Gastroenterol Hepatol (N Y).* 2019;15(3):145-54. 3. Trivella J, et al. *Hepatol Commun.* 2023;7(6):e0179. 4. Düll MM, Kremer AE. *Clin Liver Dis.* 2022;26(4):727-45. 5. Mayo MJ, et al. *Dig Dis Sci.* 2023;68(3):995-1005. 6. Althubaiti A. *J Multidiscip Healthc.* 2016;9:211-7.

Acknowledgments: We extend our gratitude to C. Fiorella Murillo Perez for her contributions to the ITCH-E study. This study was funded by Gilead Sciences, Inc. Medical writing and editorial support were provided by Ellie Manca, MPH, of Red Nucleus, and funded by Gilead Sciences, Inc.

Disclosures: CL reports receiving research grants paid to her institution from Calliditas Therapeutics; CymaBay Therapeutics; Escent Pharmaceuticals; EWR; Gilead Sciences, Inc.; GSK; Intercept Pharmaceuticals; Ipsen; Kowa; Mirum Pharma; Target RWE; and Zydus Pharmaceuticals; consulting fees from Calliditas Therapeutics; CymaBay Therapeutics; Gilead Sciences, Inc.; GSK; Intercept Pharmaceuticals; Ipsen; Kowa; and Mirum Pharma; and participation on a data safety monitoring board with COUR Pharmaceuticals. **MA, MR, WZ, and CK** are employees of Gilead Sciences, Inc., and may own stock in Gilead Sciences, Inc.

INTRODUCTION

- PBC is a chronic, autoimmune, cholestatic liver disease that disproportionately affects women and is associated with progressive liver injury and significant symptom burden¹
- Up to 80% of individuals living with PBC experience pruritus, commonly known as itching^{2,3}
- In severe cases of itching, cholestatic pruritus can become an indication for liver transplantation, even in the absence of liver failure⁴
- People who have PBC-related pruritus can experience sleep deprivation, profound fatigue, depression, social isolation, and self-mutilation, and many report substantial disability associated with their pruritus, including impairment of social life, housework/errands, and work/school^{5,6}
- Despite these known concerns associated with PBC-related pruritus, the association between pruritus severity and work productivity has never been investigated

OBJECTIVE

- To assess the relationship between pruritus severity and work productivity among employed adults with PBC in the US using data from the ITCH-E study

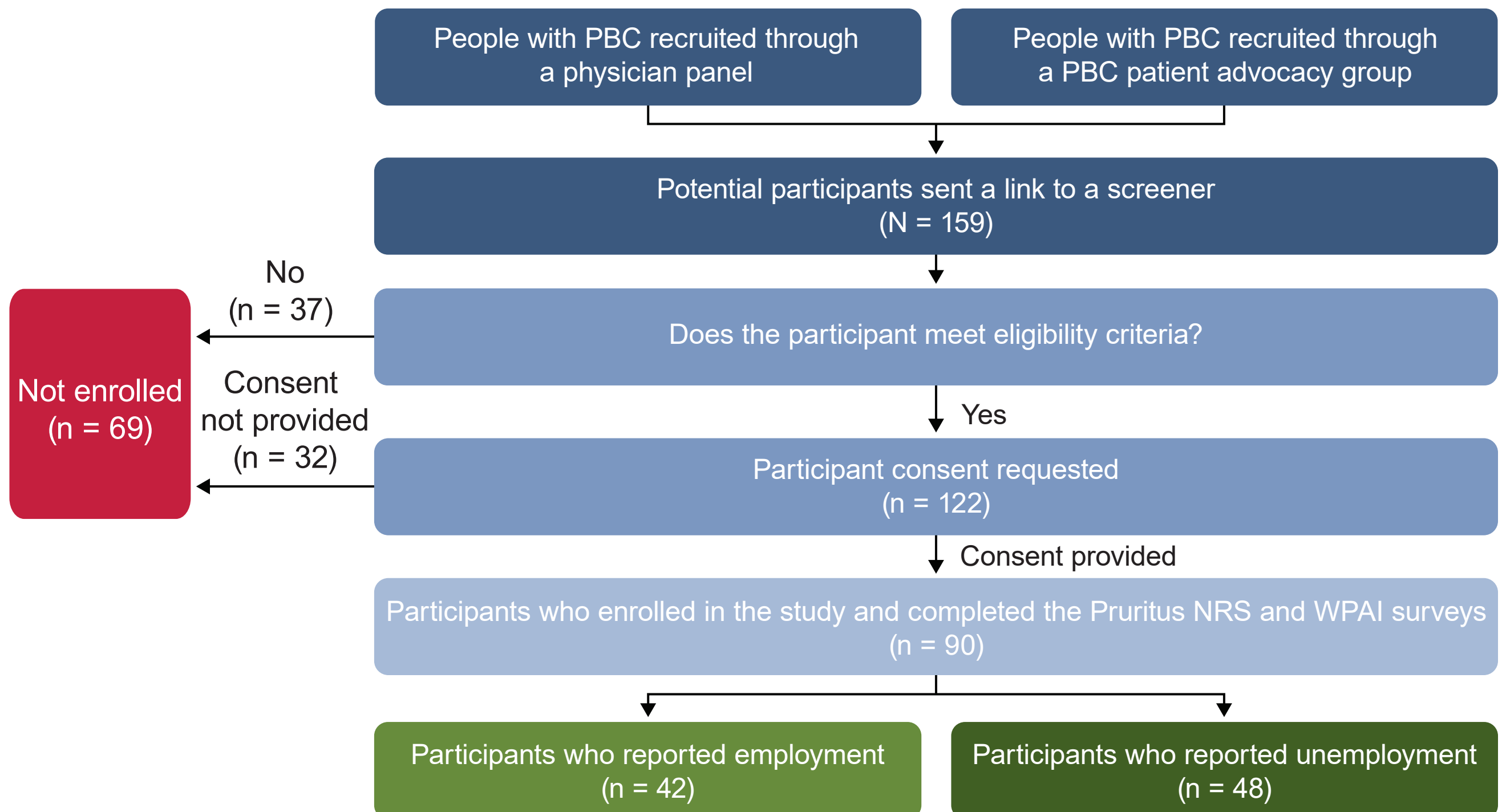
METHODS

- Adults with PBC were recruited from a PBC patient advocacy group and a physician panel between December 2023 and March 2024 as part of the ITCH-E study
 - Inclusion criteria for the ITCH-E study: PBC diagnosis, adults ≥18 years of age, currently treated with ursodeoxycholic acid or obeticholic acid, provided informed consent, and living in the US
 - Exclusion criteria for the ITCH-E study: Enrolled in a clinical trial for PBC treatment, unable to read/understand English, lacks access to a mobile device or computer, and/or affiliated with the study sponsor
- Participants completed the following questionnaires:
 - Pruritus Numerical Rating Scale (NRS)
 - Work Productivity and Activity Impairment (WPAI) Specific Health Problem V2.0, Clinical Practice Version
- To assess the relationship between pruritus severity and work productivity, this subanalysis of the ITCH-E study only included participants who were employed
 - Self-reported demographic and baseline characteristics of those who were unemployed were also examined
- Poisson generalized linear regression models were used to analyze the relationship between Pruritus NRS and WPAI
 - Participants answered the following questions to assess PBC-related and non-PBC-related lost work hours:
 - During the past seven days, how many hours did you miss from work because of problems associated with your PBC? Include hours you missed on sick days, times you went in late, left early, etc., because of your PBC
 - During the past seven days, how many hours did you miss from work because of any other reason, such as vacation or holidays?

RESULTS

- Of the 90 participants who enrolled in the ITCH-E study and completed the surveys, 47% (n = 42) reported employment (**Figure 1**)

Figure 1. Study Design and Participant Enrollment for Assessing the Relationship Between Pruritus Severity and Work Productivity



NRS, numerical rating scale; PBC, primary biliary cholangitis; WPAI, Work Productivity and Activity Impairment.

RESULTS

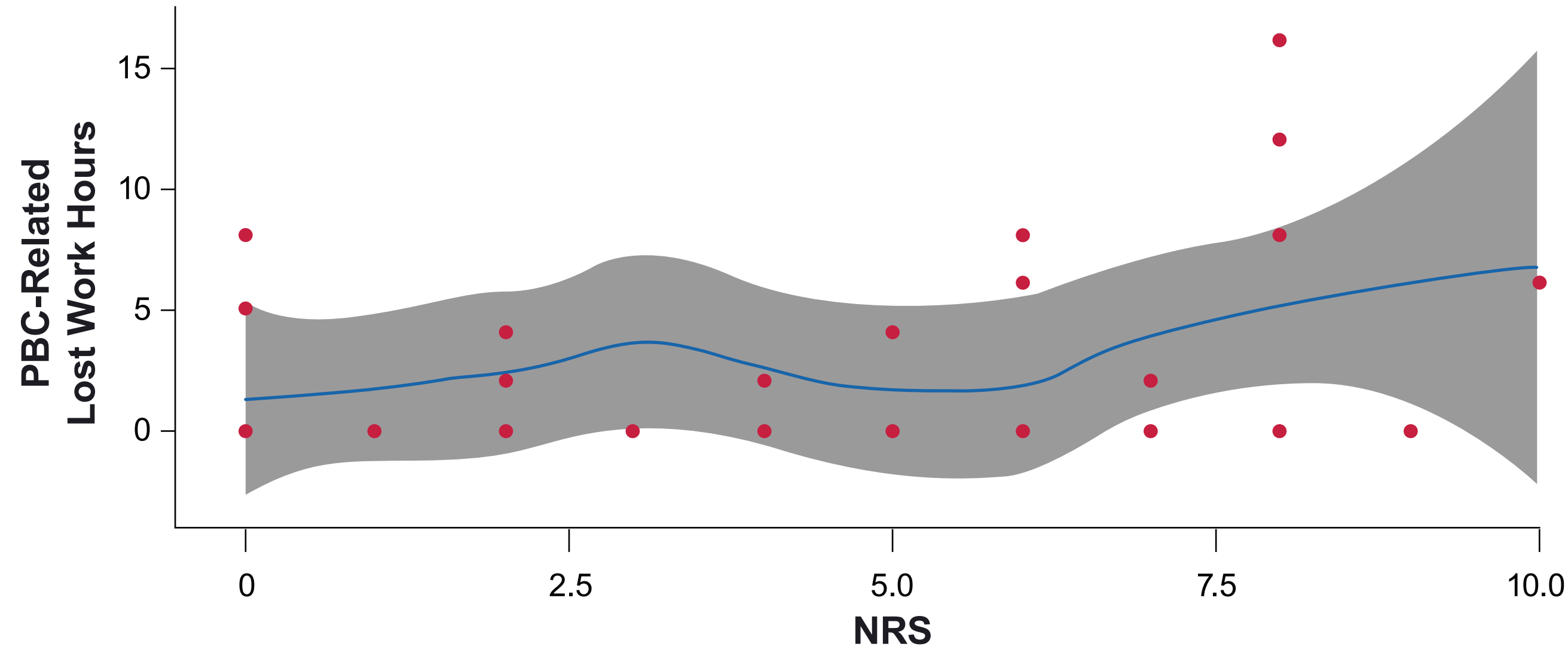
Table 1. Self-Reported Demographic and Baseline Clinical Characteristics of Employed Participants With PBC

	Employed Participants With PBC (N = 42)
Age, years, mean (SD)	51.8 (8.8)
Gender, n (%)	
Female	38 (90)
Male	3 (7)
Nonbinary	1 (2)
Race and ethnicity,* n (%)	
White	35 (83)
Hispanic or Latino	5 (12)
African American	1 (2)
Prefer not to answer	2 (5)
Participants with cirrhosis, n (%)	9 (21)
Comorbidities, n (%)	
High blood pressure	11 (26)
Anxiety	10 (24)
Raynaud syndrome	7 (17)
Diabetes	6 (14)
Asthma	4 (10)
Sjögren's syndrome	3 (7)
Lupus	2 (5)
Hypercholesterolemia	2 (5)
Fibromyalgia or chronic fatigue syndrome	2 (5)
COPD	1 (2)
Hashimoto's thyroiditis	1 (2)
Hypothyroidism	1 (2)
Limited scleroderma	1 (2)
Rheumatoid arthritis	1 (2)
Insurance, ^b n (%)	
Private	33 (79)
Other ^c	6 (14)
Medicare	2 (5)
Medicaid/CHIP	1 (2)
Prefer not to answer/I don't know	2 (5)
NRS score, mean (SD)	3.93 (2.98)
NRS ≥4, n (%)	21 (50)
NRS = 0, n (%)	8 (19)
Receiving pruritus treatment, ^d n (%)	7 (17)

*Participants could select >1 category for race and ethnicity, which explains why percentages add up to >100%.
^bSome participants reported more than 1 type of insurance.
^cOther included "Affordable Care Act subsidized," "Blue Cross/Shield," "DPC Direct Patient Care [sic] policy (inhouse) with my Dr office," "employer group plan," "Humana," and "NYS Health Exchange."
^dTreatments included antibiotics, antihistamines, fibrates, gabapentin, opiate antagonists, and sertraline.
CHIP, Children's Health Insurance Program; COPD, chronic obstructive pulmonary disease; DPC, Direct Patient Care; NRS, numerical rating scale; NYS, New York State; PBC, primary biliary cholangitis.

- Most employed participants with PBC in this study self-reported as female (90%) and White (83%), and the mean age was about 52 years (**Table 1**)
- About one-fifth of the participants (21%) had cirrhosis, and the most common comorbidities included high blood pressure (26%), anxiety (24%), and Raynaud syndrome (17%)
- Most of the participants (79%) were privately insured
- Half of the employed participants had a Pruritus NRS score ≥4, which is considered moderate to severe pruritus, and about 19% of participants had a Pruritus NRS score of 0
- Only about 17% of participants were receiving pruritus treatment, which included antibiotics, antihistamines, fibrates, gabapentin, opiate antagonists, and sertraline

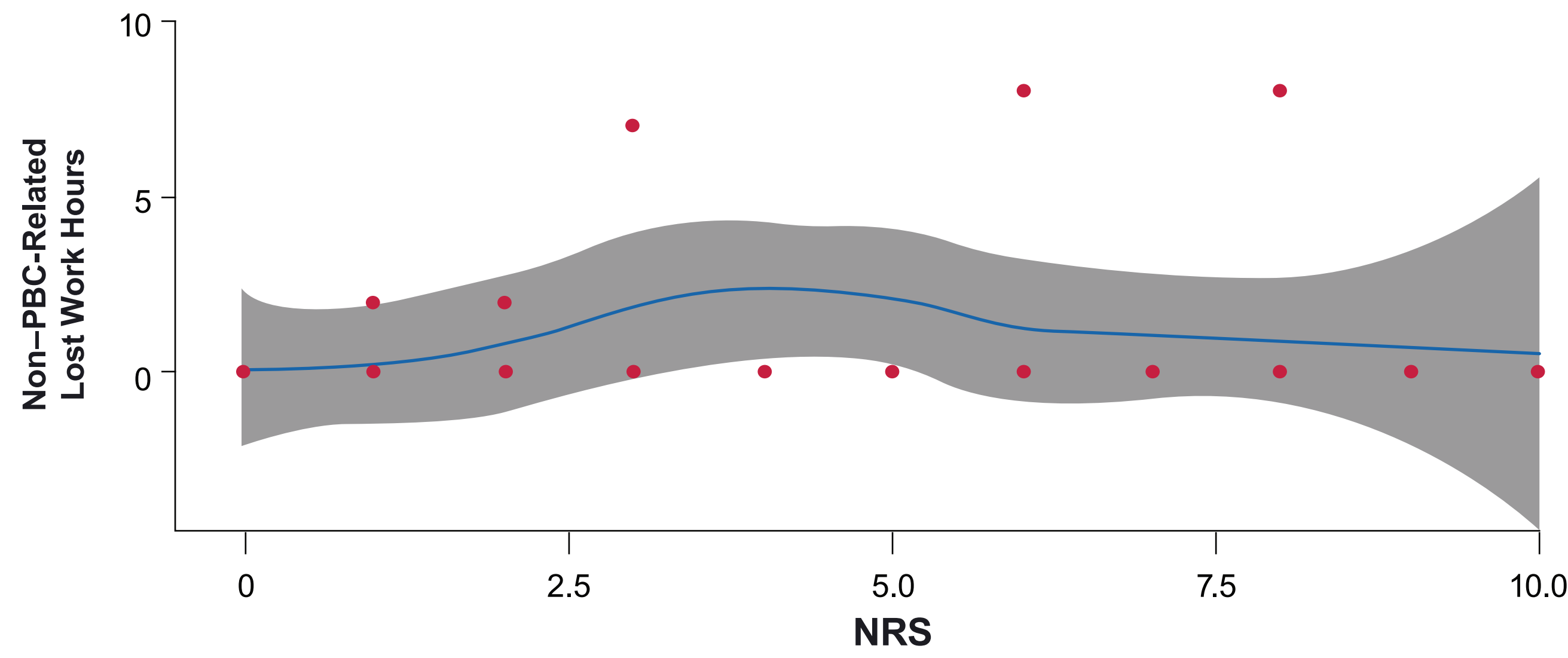
Figure 2. Association Between Pruritus NRS Score and PBC-Related Lost Work Hours^a in the Past Week^b



The blue line represents a LOWESS smoothing function that was used to fit the data during the regression analysis. The shaded gray area represents the 95% CI. Each data point represents an individual response.
^aParticipants answered the following question to assess PBC-related lost work hours: During the past seven days, how many hours did you miss from work because of problems associated with your PBC? Include hours you missed on sick days, times you went in late, left early, etc., because of your PBC.
^bOne participant with an NRS score of 3 reported 28 PBC-related lost work hours; this participant was omitted from the figure.
LOWESS, locally weighted scatterplot smoothing; NRS, numerical rating scale; PBC, primary biliary cholangitis.

- The association between Pruritus NRS score and hours missed due to PBC is shown in **Figure 2**
- Results from the Poisson regression model demonstrated that an increase in 1 unit of the Pruritus NRS score was associated with a 17% (95% CI, 10%–25%) increase in PBC-related lost work hours in the past week

Figure 3. Association Between Pruritus NRS Score and Non-PBC-Related Lost Work Hours^a in the Past Week^b



The blue line represents a LOWESS smoothing function that was used to fit the data during the regression analysis. The shaded gray area represents the 95% CI. Each data point represents an individual response.
^aParticipants answered the following questions to assess non-PBC-related lost work hours: During the past seven days, how many hours did you miss from work because of any other reason, such as vacation or holidays?
^bOne participant with an NRS score of 4 reported 16 non-PBC-related lost work hours; this participant was omitted from the figure.
LOWESS, locally weighted scatterplot smoothing; NRS, numerical rating scale; PBC, primary biliary cholangitis.

- No association was found between Pruritus NRS score and non-PBC-related work hours missed (**Figure 3**)
- Results from the Poisson regression model demonstrated that an increase in 1 unit of the Pruritus NRS score was associated with a 4% (95% CI, 3%–6%) decrease in hours worked in the past week (data not shown)
- Among participants who were not employed (n = 48), the median age was 56 years, 44% were on Medicaid, and the median score on the Pruritus NRS was 4

STRENGTHS AND LIMITATIONS

- To our knowledge, this is the first study to have investigated the association between pruritus severity and work productivity in people with PBC
- No causality can be assumed from the results of these analyses; only associations can be inferred
- In addition, self-reported survey data are inherently limited by recall bias and confounding⁶
- These analyses were not adjusted for confounders, including comorbidities and markers of disease severity such as cirrhosis
- The analyses were conducted among a small sample of employed individuals with PBC, thus further limiting their generalizability
- Of note, among those who were unemployed, more than half were younger than retirement age; further research is needed to understand whether PBC-related disease burden contributed to their unemployment status