RESEARCH LETTER

Use of Complementary Health Approaches Overall and for Pain Management by US Adults

Millions of US adults use complementary health approaches (CHAs) each year; in 2012, 55 million adults spent $28.3 billion on CHAs, comparable to 9% of total out-of-pocket health care expenditures.[1] Previously, the safety and efficacy of many of these approaches lacked rigorous clinical trials.[2] Over the past 2 decades, increasing evidence has supported the safety and efficacy of selected approaches for pain management.[3,4] We examined trends in CHA use among US adults at 3 time points: 2002, 2012, and 2022.

Supplemental content

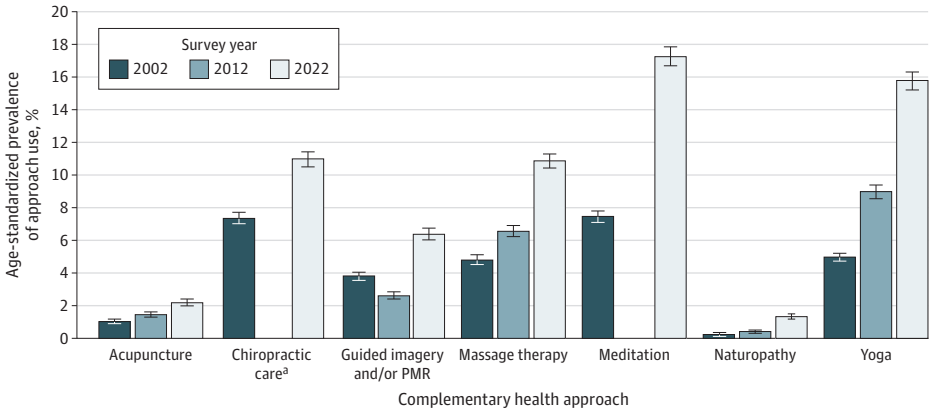
Methods | We used data from the 2002, 2012, and 2022 National Health Interview Survey (NHIS), an annual, nationally representative, cross-sectional household interview survey conducted in-person and by telephone. Response rates were 74.3% in 2002, 61.2% in 2012, and 49.6% in 2022. Increasingly sophisticated approaches to produce sample weights were used to account for nonresponse. The NHIS was approved by the National Center for Health Statistics Research Ethics Review Board, with verbal informed consent obtained.

The following approaches were consistently captured in all 3 years: acupuncture, guided imagery and/or progressive muscle relaxation, massage, naturopathy, and yoga. Questions on chiropractic care and meditation were consistently captured in 2002 and 2022. However, the questionnaire wording was substantially different in 2012, preventing comparisons with the 2002 or 2022 data. Further details on the surveys and the questions used in the present study are given in the eAppendix and eTable in Supplement 1.

Outcomes were the changes over time in use of any of the 7 CHAs and each CHA individually both for any reason and for pain management. Analyses were conducted using PROC SURVEYFREQ in SAS, version 9.4 (SAS Institute Inc). All data were age-standardized using the 2010 US Census population to allow comparisons across the survey years. We used the Cochran-Mantel-Haenszel test for linear trend to assess the significance of changes over time. Statistical significance was set at $\alpha<.05$ (2-sided), with 95% CIs presented for all prevalence estimates.

Results | There were 31 044, 34 525, and 27 651 NHIS participants in 2002, 2012, and 2020, respectively. Adults reporting use of any of the 7 approaches increased significantly between 2002 and 2022 from 19.2% (95% CI, 18.7%-19.7%) to 36.7% (95% CI, 36.0%-37.5%) ($P < .001$). Trends for all individual modalities were significant (**Figure 1**). The largest increase in utilization was seen for yoga: 5.0% (95% CI, 4.7%-5.2%) in 2002, 9.0% (95% CI, 8.6%-9.4%) in 2012, and 15.8% (95% CI, 15.2%-16.3%) in 2022. The CHA with the highest prevalence was meditation, used by 17.3% (95% CI, 16.7%-17.9%) of individuals in 2022. Use of acupuncture, which was increasingly covered by insurance, increased from 1.0% (95% CI, 0.9%-1.2%) in 2002 to 1.5% (95% CI, 1.3%-1.6%) in 2012 and 2.2% (95% CI, 2.0%-2.4%) in 2022.

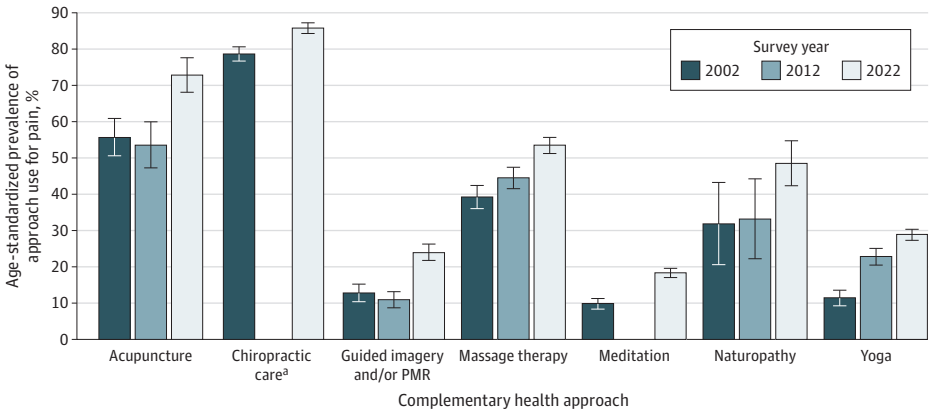
Figure 1. Age-Standardized Prevalence of Use of Complementary Health Approaches by US Adults in 2002, 2012, and 2022



Data are from the 2002 (n = 31 044), 2012 (n = 34 525), and 2022 (n = 27 651) National Health Interview Survey (NHIS). Prevalence was estimated using survey weights supplied by the National Center for Health Statistics. All estimates are age-standardized to the age distribution of the US population in 2010 to allow comparisons across years. Questions about the use of chiropractic care and meditation in the 2012 NHIS were sufficiently different from questions in 2002 and 2022, such that prevalence comparisons could not be made (eTable in Supplement 1). The significance of changes over time was assessed using the Cochran-Mantel-Haenszel test for linear trend. $P < .001$ for all comparisons. Error bars represent 95% CIs. PMR indicates progressive muscle relaxation.

[a] Data from 2012 are not available.

Figure 2. Age-Standardized Prevalence of Use of Complementary Health Approaches for Pain Management Among Adults Using Each Approach in 2002, 2012, and 2022



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Among participants reporting use of any of the 7 approaches, the percentage reporting use for pain management increased significantly from 42.3% (95% CI, 40.8%-43.8%) in 2002 to 49.2% (95% CI, 48.0%-50.3%) in 2022. Trends for use of all individual CHAs for pain management were statistically significant. Of the 7 approaches, adults practicing yoga reported the largest increase in use for pain management, from 11.4% (95% CI, 9.3%-13.6%) in 2002 to 22.8% (95% CI, 20.4%-25.1%) in 2012 and 28.8% (95% CI, 27.3%-30.4%) in 2022. The CHA with the highest use for pain management was chiropractic care (85.7% [95% CI, 84.2%-87.2%] in 2022) (**Figure 2**).

Discussion | Between 2002 and 2022, US adults increasingly used CHAs, including for pain management. This shift in utilization coincides with increased pain prevalence nationally[5] and may be attributable to several factors, including randomized clinical trials suggesting that some CHAs provide low to moderate levels of pain management,[3] incorporation of CHAs into best practice pain management guidelines,[4] and the need to mitigate unnecessary use of potentially harmful opioids through use of nonopioid interventions. Insurance coverage for acupuncture also increased during this period, expanding patient access.[6] Study limitations include decreasing NHIS response rates over time, possible recall bias, use of cross-sectional data, and differences in how CHAs and their use for pain management were queried across survey years.

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Drafting of the manuscript: Rhee.
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HEALTH AND THE 2024 US ELECTION

Premarket Notifications and Patents for Breast Pumps Before and After the ACA

Innovation in medical products for maternal health has been slow partly due to underfunding of research to advance scientific understanding of women's health.[1] The Patient Protection and Affordable Care Act (ACA),[2] enacted in March 2010, required employers to provide employees who are breastfeeding a reasonable break time and appropriate location to express milk. A second provision, which became effective in August 2012, required all new insurance policies to provide coverage for preventive services, including breast pumps and lactation care, with no cost sharing. Beginning January 2014, this coverage was extended to insurance acquired through marketplace plans and in states that expanded Medicaid.[3] This study investigated whether these ACA policies to increase access to breast pumps and lactation care were associated with innovation in the market for breast pumps.

Supplemental content

Methods | We examined changes between 1994 and 2021 in 2 outcome variables: (1) number of patent filings and (2) number of 510(k) premarket notifications (PMNs) for breast pumps. Breast pumps are classified as Class II medical devices by the US Food and Drug Administration (FDA). While a patent filing requests exclusive right to an invention, a PMN seeks to demonstrate that the device is safe and effective. Firms are required to submit a PMN before marketing a breast pump in the US. Data on patent filings were obtained from the PatentsView dataset, US Patent and Trademark Office, and data on PMNs were obtained from the Premarket Notification 510(k) dataset from the FDA. Using the itsa package in Stata, version 16.1 (StataCorp), we specified interrupted time series analyses (ITSAs) to assess the statistical significance of the change in trends before ACA (1994-2009) vs after ACA (2010-2021) for outcomes. ITSA estimates coefficients with ordinary least-squares regression and produces Newey-West standard errors to correct for autocorrelation and possible heteroscedasticity. For patent filings, the model assumes 2 interruptions (ACA and COVID-19 pandemic). While patent filings occur in early-stage research that was disrupted by the COVID-19-pandemic,[4] PMNs are part of product launch, which is less likely to be disrupted. We produced trendline plots with ITSA estimates and reported 95% CIs. $P < .05$ (2-sided) was considered statistically significant.

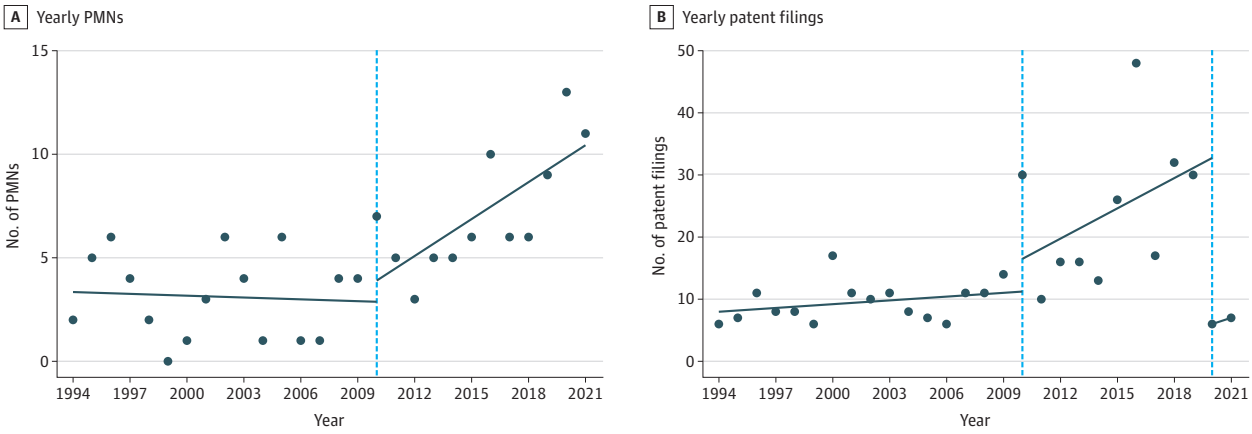
Results | There were 136 PMNs and 403 patent filings for breast pumps (**Table**) between 1994 and 2021. Of 136 PMNs, 121 (89.0%) were for new breast pumps. Before ACA, 20 of 25 firms (80.0%) submitted a PMN for the first time compared with 38 of 44 firms (86.4%) after ACA.

Table. Summary Statistics for Premarket Notifications and Patent Filings for Breast Pumps Before and After ACA, 1994-2021

	Before ACA (1994-2009)		After ACA (2010-2021)	
Parameter	Total No.	Yearly mean No.	Total No.	Yearly mean No.
Patent filings for breast pumps	152	9.50 (0.77)	251	20.92 (3.60)
Premarket notifications for breast pumps	50	3.13 (0.51)	86	7.17 (0.85)

Abbreviation: ACA, Patient Protection and Affordable Care Act.

Figure. Interrupted Time Series Analyses (ITSAs) for Yearly Premarket Notifications (PMNs) and Patent Filings for Breast Pumps Before and After the Patient Protection and Affordable Care Act (ACA), 1994-2021



Trendline estimates were the ITSA regression with Newey-West 95% CIs. A, Interruption specified at 2010 (ACA) (dashed line). Pre-ACA trend (slope), −0.03 (95% CI, −0.22 to 0.16; $P = .75$). Change in number of PMNs in 2010, 1.02 (95% CI, −1.29 to 3.34; $P = .37$). Post-ACA trend (slope) compared with pre-ACA trend, 0.62 (95% CI, 0.16-1.08; $P = .01$). B, Interruption specified at 2010 (ACA) and 2020 (COVID-19 pandemic) (dashed lines). Pre-ACA trend (slope), 0.20 (95% CI, −0.04 to 0.44; $P = .09$). Change in number of patent filings in 2010, 5.27 (95% CI, −2.57 to 13.10; $P = .18$). Post-ACA trend (slope) compared with pre-ACA trend, 1.42 (95% CI, 0.20-2.64; $P = .02$). Change in number of patent filings in 2020, −26.73 (95% CI, −33.29 to −20.17; $P < .001$).