



A Topical Botanical Ointment for Self-Reported Hip and/or Knee Pain: A Randomized Placebo-Controlled Clinical Trial

Richard J. Bloomer, PhD¹ , Jacquelyn Pence, PhD¹,
Roddy Morris Jr., MS¹, Michelle B. Stockton, PhD¹,
and Allyson Signaigo, BS¹

Abstract

Joint pain is a common ailment among adults worldwide. Six men and 14 women (aged 51 ± 10 years) with self-reported joint pain were randomly assigned, using a cross-over design, to a botanical ointment (Yeahhh Baby![®]) or placebo, twice daily for 14 days. Subjects completed questionnaires regarding their joint pain and discomfort (eg, WOMAC and subjective pain using a visual analog scale [VAS]) each evening and underwent a washout period of two weeks before crossing into the other condition. Pain and discomfort scores improved for subjects when using Yeahhh Baby![®] ointment from day 1 to the average of days 2-15. For certain measures, similar, albeit insignificant, improvements were noted when subjects used the placebo—demonstrating the powerful placebo effect. Specifically, with Yeahhh Baby![®] ointment, effects were noted for WOMAC pain ($P = .008$), WOMAC physical function ($P = .024$), WOMAC total ($P = .019$), and VAS mood interference ($P = .042$). The most pronounced improvement was noted for WOMAC pain ($P = .048$), with a 25% reduction observed with Yeahhh Baby![®], with a 10% reduction noted for placebo. These findings indicate that, as compared to a placebo, Yeahhh Baby![®] ointment may provide relief to individuals suffering from joint pain in their knees and/or hips.

Keywords

joint pain, analgesic, topical ointment, Yeahhh Baby!

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Introduction

Chronic joint pain and discomfort are commonplace for those with and without arthritis, with a noted 14.6 million arthritic Americans suffering from severe joint pain in 2014¹ and 17.5% of American adults reporting joint pain not associated with arthritis.² With the high prevalence of joint pain among adults in the United States, it is not surprising that a variety of options are available for joint pain treatment, including topical creams and ointments that offer expedient pain relief.^{3,4,5}

In fact, the topical pain relief market is expected to reach \$3.27 billion in 2021.⁶ Topical treatments are popular due to their ability to be administered directly to the site of pain, in addition to the perception that they are less likely to have

adverse systemic effects as compared to oral medications.⁷ Popular topical ointments currently marketed specifically for joint pain relief include Bengay[®], Icy Hot[®], Jointflex[®], and Aspercreme[®]. These products utilize a combination of widely accepted analgesic ingredients including capsaicin, salicylates, menthol, camphor, and lidocaine to reduce pain.^{8,9}

¹ Center for Nutraceutical and Dietary Supplement Research, College of Health Sciences, University of Memphis, Memphis, TN, USA

Corresponding Author:

Richard J. Bloomer, University of Memphis, 106 Roane Fieldhouse, Memphis, TN 38152, USA.
Email: rbloomer@memphis.edu



Despite the popularity of existing topicals, some individuals may prefer treatment options that are all-natural, with origins in botanical medicine. For example, the market for herbal medicine is anticipated to be six to seven times the 2019 market by 2030, as more people turn to all-natural herbal-based medicines for a variety of health benefits,¹⁰ including antioxidant,¹¹ anti-inflammatory,¹² blood glucose¹³ and lipid-lowering activities,¹⁴ in addition to improved sleep¹⁵ and cognitive performance.¹⁶

The healthcare market for natural products is prevalent worldwide in both developing and developed countries alike.¹⁷ According to the results from the 2012 National Health Interview Survey, 6.7% of American adults who reported using complimentary health approaches did so for joint pain and stiffness,¹⁸ and nearly a quarter of American adults with musculoskeletal pain used a natural product as part of their healthcare regimen.² Additionally, a report on the 2015 National Consumer Survey on Medication Experience and Pharmacist Role (NCSME-PR) found that of the 26.6% of respondents who reported having arthritis, 43% reported using an herbal medicine.¹⁹

Yeahhh Baby!® ointment is an herbal (botanical: plant-based) treatment for those suffering from joint pain. The

product has been sold since 2016 and is marketed as an all-natural alternative to other commercially available products. The ointment consists primarily of coconut oil (98%) with magnesium and small amounts of herbal ingredients including nigella seed, sweet weed, Indian pink, green ginger, velvet plank, kidney wort, mad dogweed, slippery root, tanner bark, and walnut hulls. These ingredients have been used in botanical medicine, specifically for their anti-inflammatory and healing properties. While multiple anecdotal reports of effectiveness exist, no controlled studies to date have investigated the efficacy of the Yeahhh Baby!® product to alleviate joint pain and related measures.

The present study sought to compare the effect of Yeahhh Baby!® to a placebo ointment on joint pain and discomfort in men and women who regularly experience hip and/or knee joint pain. We hypothesized that perceived pain and discomfort would be reduced when subjects used the Yeahhh Baby!® ointment for a period of 14 days.

Methods

All procedures were approved by the University of Memphis Institutional Review Board for Human Subjects Research (protocol PRO-FY2021-94) and the study was registered through clinicaltrials.gov. Close to 100 individuals expressed interest in participating but only 24 met all study criteria. A total of 20 subjects were eventually enrolled and completed the study. Subjects were required to be between 35 and 65 years old, non-tobacco users, not obese (body mass index under 30 kg/m²), with self-reported knee and/or hip pain with a minimum pain rating of 3/10 for at least the 30 days prior to study enrollment. The majority of subjects noted knee pain (n=13) or a combination of knee and hip pain (n=5), with only two subjects reporting hip pain exclusively. Subject were required to be non-users of anti-inflammatory medicines, pain medications, or dietary supplements (or willing to cease for one-month prior to participation and throughout study) and could not be allergic to coconut, walnuts, oak, or olives. Female subjects were not pregnant. Subjects were compensated \$200 for their full participation. Subject baseline descriptive characteristics are presented in Table 1.

During the initial visit to the laboratory, subjects completed the informed consent form, health history, medication and dietary supplement usage, physical activity, and joint pain questionnaires. Subjects' heart rate, blood pressure, height, weight, waist and hip circumferences were measured. To confirm non-pregnancy, females were provided with a urine pregnancy test kit (AccuMed®, Houston, Texas, USA), escorted to a private restroom (within the lab), and asked to perform the test, which was then assessed and confidentially confirmed by the investigators. Eligible subjects were scheduled for bi-weekly testing visits after screening was completed.

Subjects reported to the lab every two weeks for a total of four lab visits. One half of the subjects were randomly assigned to start on the Yeahhh Baby!® ointment and the other half on the placebo ointment. The Yeahhh Baby!® ointment consisted primarily of coconut oil (98%), with small amounts of herbal ingredients (tanner's bark, slippery root, sweet weed, velvet plant, walnut hulls, kidney root, green ginger, Indian pink, mad dogweed, and nigella seed). The placebo consisted primarily of coconut oil with a small amount of olive oil added to make it easier to apply on the skin. Both the investigators and the subjects were blinded to which condition was the active treatment and which was the placebo.

Table 1. Baseline Subject Characteristics Prior to Receiving Either Treatment or Placebo.

Characteristics	Values (mean [SD] or n [%])
Age (yrs)	51.4 (9.8)
Gender, n (%)	
Male	6 (30.0)
Female	14 (70.0)
Height (cm)	170.3 (11.8)
Weight (kg)	74.1 (16.0)
BMI (kg·m ⁻²)	25.4 (3.1)
Waist (cm)	87.0 (21.5)
Hip (cm)	101.7 (18.9)
Waist/Hip	0.86 (0.16)
Systolic Blood Pressure (mm Hg)	126.8 (11.6)
Diastolic Blood Pressure (mm Hg)	82.6 (11.1)
Heart Rate (bpm)	71.3 (11.6)
Pain (0-10; no pain-extreme pain)	5.0 (1.4)
Pain Location	
Hip	2 (10)
Knee	13 (65)
Hip and Knee	5 (25)
Joint Health (WOMAC)	
WOMAC Pain	9.0 (2.6)
WOMAC Stiffness	4.2 (1.6)
WOMAC Physical Function	27.6 (11.7)
WOMAC Total	40.8 (14.9)
VAS Pain (100 mm scale)	
VAS Joint Pain	63.4 (24.4)
VAS Work Interference	41.1 (29.1)
VAS Recreational Activity Interference	62.0 (26.8)
VAS Mood Interference	48.5 (30.8)
VAS Total Average	53.7 (18.9)

On day 1 of each treatment, while in the lab, subjects were instructed as to how to apply the assigned ointment to the affected area(s), including the amount of ointment to use (approximately the size of a quarter). They were instructed to apply the same amount of ointment to each affected area (knees and/or hips), and this was the same for both treatment and placebo conditions. They were instructed to do this twice daily—morning and evening throughout the course of the study. In addition, subjects were provided instruction as to how to complete the at-home questionnaires specific to their joint health and the degree of joint pain experienced during various daily activities. Specifically, we used the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), commonly used to assess the effects of osteoarthritis on pain, stiffness, and physical function within individuals, as well as a questionnaire developed to assess hip/knee joint pain. The latter questionnaire used a visual analog scale (VAS) that asked subjects to mark on the scale from 0 to 100 how much they disagreed (0) or agreed (100) with each of 4 statements: 1) In the past 24 h, I have experienced significant knee/hip joint pain. 2) In the past 24 h, my knee/hip joint pain has interfered with my work. 3) In the past 24 h my knee/hip joint pain has interfered with my recreational activities. 4) In the past 24 h, my knee/hip joint pain has negatively impacted my mood/attitude. While in the lab, subjects also had their resting blood pressure and heart rate measured using an automated unit (OMRON HEM 907XL, OMRON Healthcare, Tokyo, Japan), following a 10-min seated rest period, with the average of duplicate measures recorded at each time.

On day 15 of each treatment, subjects again reported to lab without applying the ointment with the remaining ointment and their completed joint pain questionnaires (WOMAC and VAS) with them to the visit. In lab, the subjects again completed the two questionnaires, and blood pressure and heart rate were again measured following a 10-min seated rest period. A 14-day wash-out period separated each condition assignment. Subjects then crossed into the other condition and the methods above were repeated. During the entire study period, subjects were instructed to maintain their usual lifestyle and activity patterns, without beginning any new exercise or physical activity program for the alleviation of joint pain. Please see Figure 1 for an overview of the study.

Statistical Analysis

Blood pressure and heart rate were analyzed with two-factor repeated measures ANOVA. Two-way repeated measures ANOVAs were also used to determine whether there were any changes in the outcome variables for WOMAC and VAS as the result of the interaction between the type of treatment (ointment vs placebo) and time (day 1 compared to the average score for days 2 through 15). Analyses of the studentized residuals showed that the data were normally distributed with no outliers, as assessed by the Shapiro-Wilk test and no studentized residuals greater than +3 standard deviations. In the event of significant main effects or interactions, planned pairwise comparisons were made to identify differences among mean value time points. Lastly, separate pairwise comparisons were conducted using repeated measures t-tests to evaluate univariate differences from Day 1 to the average of Days 2 through 15 for the outcome variables for ointment condition and placebo condition, respectively. The alpha level for all statistical tests was set at $p \leq 0.05$. Statistical analyses were completed using the SPSS software (Version 26.0, SPSS, Inc. Chicago, IL). Data are presented as mean \pm SD unless otherwise noted.

Results

A total of 20 subjects completed both visits for each of the two test conditions. Of the 20 subjects, 6 were men and 14 were women. No attempt was made to compare results between genders, as the focus of the study was on the influence of the treatment versus placebo. No adverse events were noted, and all subjects tolerated the treatment very well. An additional subject started the study but completed only 1 study visit before becoming uncontactable; data for this subject are not included. During screening, two subjects indicated that pain was located primarily in their hips, 13 subjects indicated that pain was located primarily in their knees, and five subjects indicated pain in both the hips and knees. Table 1 provides details of the baseline values for pain and associated variables.

Heart Rate and Blood Pressure

For heart rate, systolic blood pressure, and diastolic blood pressure, no significant time by treatment interactions were detected ($P = .874, .635, \text{ and } .836$ respectively) nor were any treatment effects ($P = .395, .886, \text{ and } .635$ respectively) or time effects ($P = .638, .0701, .635$ respectively) noted. Data for blood pressure and heart rate are presented in Figure 2.

Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

A significant treatment by time interaction was noted for changes in the WOMAC pain score, $F(1,19) = 4.465, P = .048$, partial $\eta^2 = 0.190$ (Table 2). Further analysis found no significant main effects of treatment ($P > .05$). However, there was a significant main effect of time on the WOMAC pain score. WOMAC pain was statistically significantly lower for the treatment intervention from Day 1 ($M = 6.98, SE = 0.67$) compared to the average score for days 2 through 15 ($M = 5.23, SE = 0.65$), $F(1, 19) = 8.85, P = .008$, a mean difference of 1.72, 95% CI [.510, 2.931]. WOMAC pain was not statistically significantly different for the control placebo condition between Day 1 ($M = 6.43, SE = 0.76$) compared to the average score for days 2 through 15 ($M = 5.78, SE = 0.69$), $F(1, 19) = 1.22, P = .283$, a mean difference of 0.65, 95% CI [-.579, 1.875]. This corresponded to a 25% reduction in pain observed with the Yeahhh Baby!® treatment from day 1 to the average of days 2-15 ($P = .008$; Table 3), while the 10% reduction for placebo was noted ($P = .283$; Table 4).

No significant treatment by time interactions (Table 2) were observed for WOMAC Stiffness, WOMAC Physical Function, and WOMAC Total ($P = .806, .943, .873$). An effect of time was observed for WOMAC Physical Function and WOMAC Total ($P = .010 \text{ and } .008$).

With Yeahhh Baby!® ointment, effects were noted for WOMAC pain ($P = .008$; effect size = 0.665), WOMAC physical function ($P = .024$; effect size = 0.547), and WOMAC total ($P = .019$; effect size = 0.593); see Table 3. For placebo, WOMAC physical function ($P = .061$) and WOMAC total

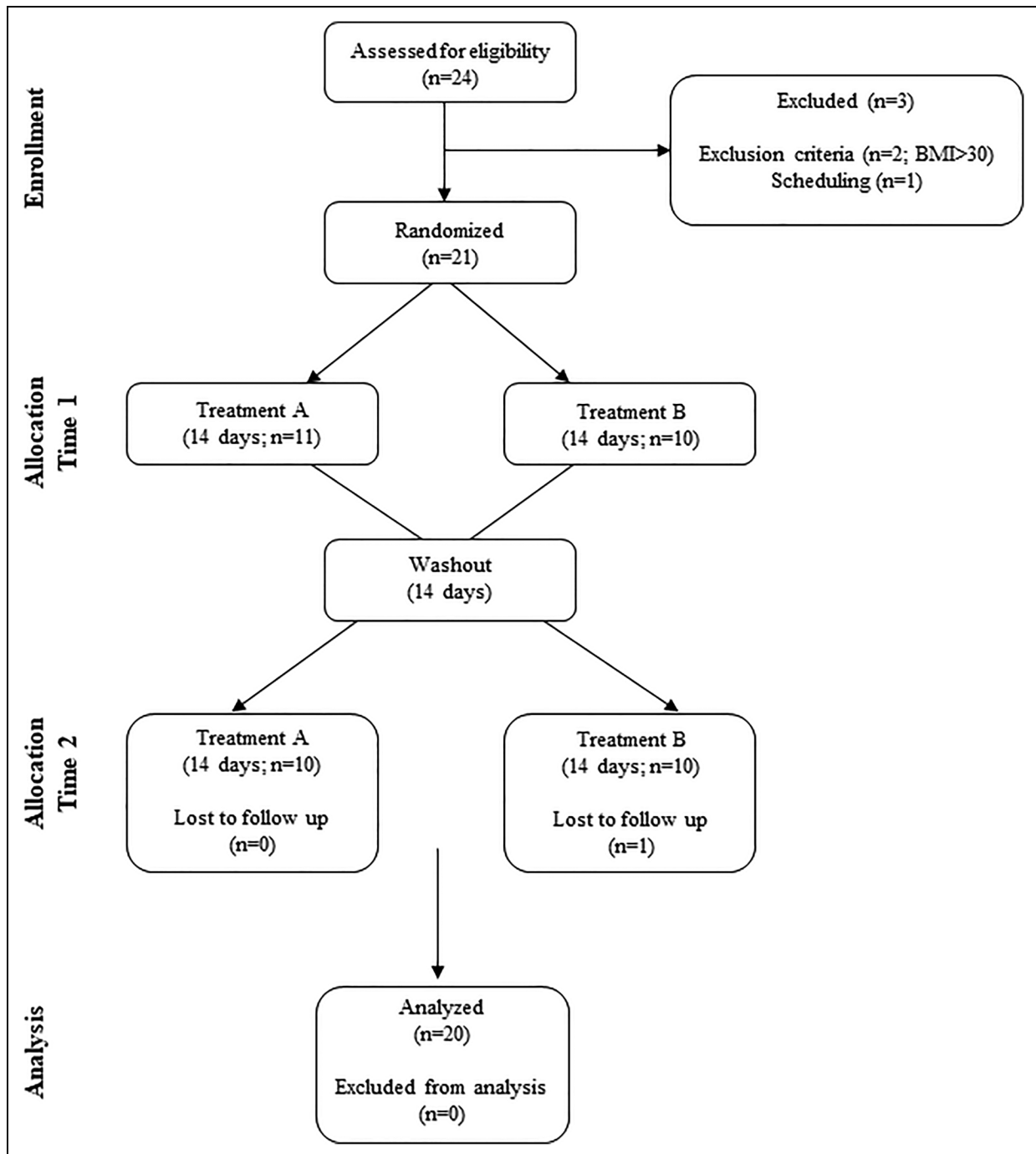


Figure 1. CONSORT flow diagram of study.

($P = .057$) approached statistical significance, but no other measures were of significance ($P > .05$); see Table 4.

Visual Analog Scale

For the VAS variables (Joint Pain, Work Interference, Recreational Activity Interference, Mood Interference, and Total), no significant treatment by time interactions (Table 2) were observed ($P = .319, .888, .966, .668$, and

$.600$, respectively) nor were there any significant effects of treatment ($P = .636, .609, .835, .334$, and $.898$) or time ($P = .276, .509, .336, .146$, and $.258$). The Yeahhh Baby!® ointment resulted in a 16% improvement in mood interference from day 1 to days 2-15 (Table 3), which was of statistical significance ($P = .042$; effect size = 0.487). No other differences for either treatment or any variable were of significance ($P > .05$), as can be seen in Tables 3 and 4.

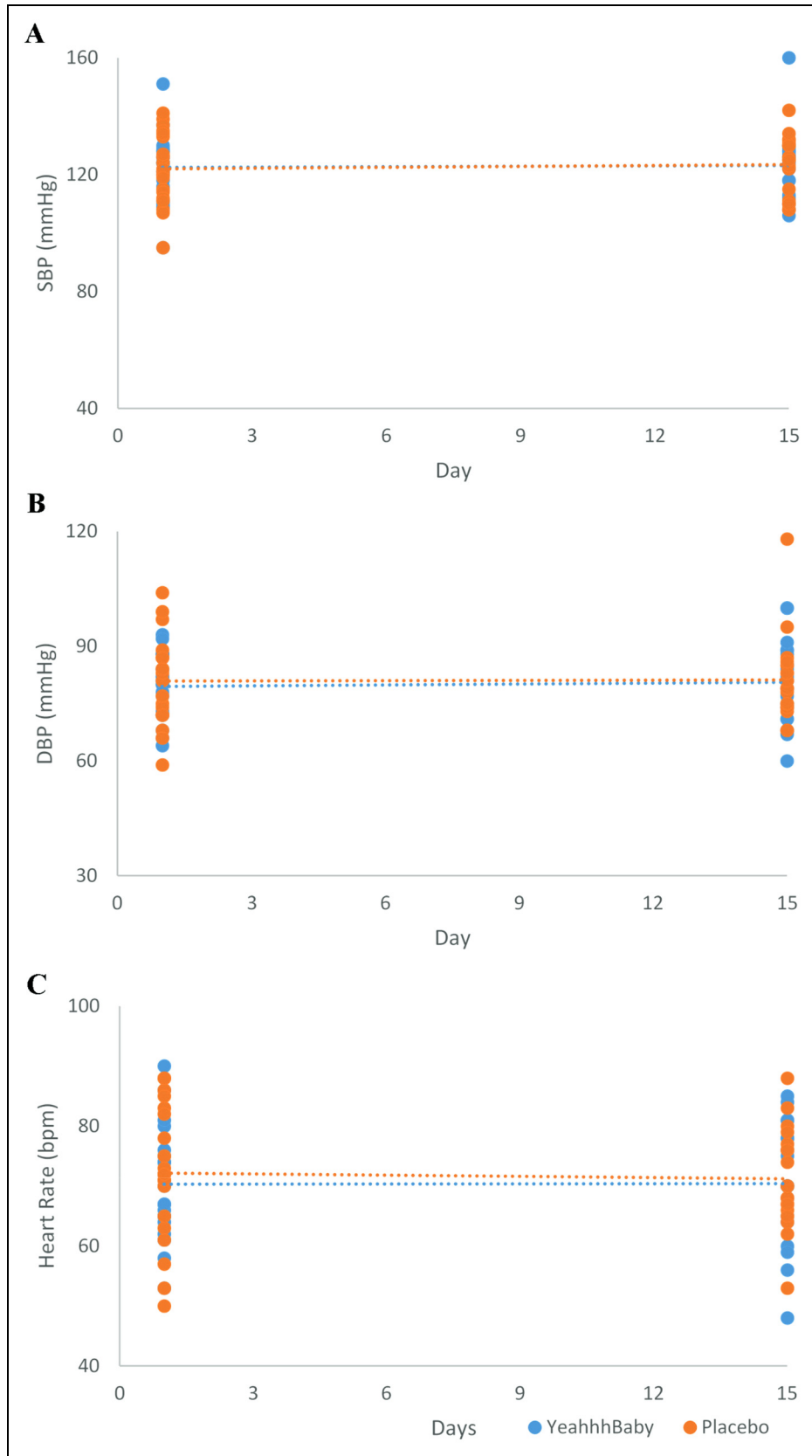


Figure 2. Blood pressure and heart rate of subjects on days 1 and 15 of treatment. No significant interactions were detected for any variable ($P > .05$).

Table 2. Multivariate Outcomes for Treatment by Time for Day 1 Compared to Average Scores for Days 2 Through 15 for the Yeahhh Baby!® Ointment Versus the Placebo.

Outcome Measurement	Yeahhh Baby!® Ointment (Mean ± SD)	Placebo (Mean ± SD)	P-value
WOMAC Pain			.048*
Day 1	6.98 ± 3.00	6.43 ± 3.40	
Average Days 2-15	5.25 ± 2.91	5.77 ± 3.10	
WOMAC Stiffness			.806
Day 1	2.95 ± 1.87	2.95 ± 1.65	
Average Days 2-15	2.83 ± 1.43	2.71 ± 1.71	
WOMAC Physical Function			.943
Day 1	21.10 ± 11.23	21.43 ± 11.19	
Average Days 2-15	16.92 ± 10.94	17.42 ± 10.67	
WOMAC Total			.873
Day 1	30.76 ± 15.53	31.88 ± 15.33	
Average Days 2-15	24.72 ± 14.91	25.23 ± 14.84	
VAS1 Joint Pain			.319
Day 1	48.09 ± 25.94	43.69 ± 26.80	
Average Days 2-15	41.16 ± 24.62	41.80 ± 28.60	
VAS2 Work Interference			.888
Day 1	37.08 ± 28.36	39.35 ± 27.70	
Average Days 2-15	35.06 ± 27.55	36.56 ± 25.36	
VAS3 Recreational Activity Interference			.966
Day 1	49.70 ± 31.79	48.55 ± 30.00	
Average Days 2-15	45.58 ± 27.73	44.73 ± 27.17	
VAS4 Mood Interference			.668
Day 1	38.17 ± 32.20	42.53 ± 32.86	
Average Days 2-15	31.62 ± 28.15	38.26 ± 27.14	
VAS Total			.600
Day 1	43.62 ± 26.33	42.79 ± 28.62	
Average Days 2-15	38.15 ± 24.88	40.05 ± 26.24	

*P < .05.

Discussion

The present study determined the ability of an all-natural ointment to alleviate joint pain and discomfort. Our findings demonstrate the effectiveness of the Yeahhh Baby!® ointment to reduce pain in middle-aged men and women who experience regular joint pain.

Few research studies to date have explored the effects of natural topicals for the treatment of joint pain, with varying results noted. Among the purely herbal remedies tested, arnica extract and comfrey extract have shown promise,²⁰ with some favorable findings also noted for capsaicin and menthol.²¹ Recently, Jamali and colleagues determined the effect of a curcumin 5% ointment on knee pain in adults with osteoarthritis, with a noted medium effect.²²

Other studies have combined herbal components with common analgesics already widely used. Glucosamine combined with capsaicin showed a decrease in joint pain, however the study lacked a placebo control.²³ In a pair of studies,

Table 3. Univariate Outcomes for Repeated Measures t-Test for Yeahhh Baby!® Ointment Condition (Day 1 vs Average of Days 2-15).

Outcome Measurement	Yeahhh Baby!® Ointment (Mean ± SD)	P-value	Effect Size
WOMAC Pain		.008*	.665
Day 1	6.98 ± 3.00		
Average Days 2-15	5.25 ± 2.91		
WOMAC Stiffness		.697	.091
Day 1	2.95 ± 1.87		
Average Days 2-15	2.83 ± 1.43		
WOMAC Physical Function		.024*	.547
Day 1	21.10 ± 11.23		
Average Days 2-15	16.92 ± 10.94		
WOMAC Total		.019*	.593
Day 1	30.76 ± 15.53		
Average Days 2-15	24.72 ± 14.91		
VAS1 Joint Pain		.120	.364
Day 1	48.09 ± 25.94		
Average Days 2-15	41.16 ± 24.62		
VAS2 Work Interference		.653	.102
Day 1	37.08 ± 28.36		
Average Days 2-15	35.06 ± 27.55		
VAS3 Recreational Activity Interference		.476	.163
Day 1	49.70 ± 31.79		
Average Days 2-15	45.58 ± 27.73		
VAS4 Mood Interference		.042*	.487
Day 1	38.36 ± 31.35		
Average Days 2-15	32.26 ± 27.55		
VAS Total		.198	.298
Day 1	43.32 ± 25.66		
Average Days 2-15	38.51 ± 24.27		

*P < .05.

Arthritis Relief Plus cream which contains both menthol and capsaicin in addition to a botanical blend (brewer's yeast, comfrey, common fallow laurel, English oak, fenugreek, kelp, Solomon's seal, tumeric, and winter cherry) was found to improve joint pain over a placebo.^{21,24} Joint-Ritis was also tested for joint pain amelioration.²⁵ The product, which contains multiple ingredients (menthol, essential oils, chondroitin sulfate, glucosamine sulfate, lanolin) did not result in any reduction in pain as compared to a placebo.

The herbal blend in Yeahhh Baby!® ointment was developed specifically for joint pain. Unlike some previously studied botanical topicals for joint pain, Yeahhh Baby!® ointment is all-natural and doesn't contain other commercially popular analgesics like capsaicin or menthol. Tanner's bark (*Quercus robur*), velvet plant (*Verbascum thapsus*), walnut hulls, kidney root (*Eupatorium purpureum*), green ginger (*Artemisia absinthium*), nigella seed (*Nigella sativa*), slippery root (*Symphytum officinale*), sweet weed (*Althea officinalis*) have all previously been found to have anti-inflammatory and/or analgesic properties.

In the present study, subjects reported a significant joint pain alleviation when using the Yeahhh Baby!® for a period of two

Table 4. Univariate Outcomes for Repeated Measures t-Test for Placebo Condition (Day 1 vs Average of Days 2-15).

Outcome Measurement	Placebo Ointment® (Mean ± SD)	P-value	Effect Size
WOMAC Pain		.283	.248
Day 1	6.43 ± 3.40		
Average Days 2-15	5.78 ± 3.10		
WOMAC Stiffness		.542	.142
Day 1	2.95 ± 1.65		
Average Days 2-15	2.71 ± 1.71		
WOMAC Physical Function		.061	.445
Day 1	21.43 ± 11.19		
Average Days 2-15	17.42 ± 10.67		
WOMAC Total		.057	.467
Day 1	31.88 ± 15.33		
Average Days 2-15	25.23 ± 14.94		
VAS1 Joint Pain		.709	.085
Day 1	43.69 ± 26.80		
Average Days 2-15	41.80 ± 28.60		
VAS2 Work Interference		.547	.137
Day 1	39.35 ± 27.70		
Average Days 2-15	36.56 ± 25.36		
VAS3 Recreational Activity Interference		.461	.168
Day 1	48.55 ± 30.00		
Average Days 2-15	44.73 ± 27.17		
VAS4 Mood Interference		.450	.177
Day 1	42.56 ± 32.86		
Average Days 2-15	38.26 ± 27.14		
VAS Total		.580	.129
Day 1	42.79 ± 28.62		
Average Days 2-15	40.05 ± 26.24		

*P < .05.

weeks, as assessed by WOMAC. Subjects also reported that Yeahhh Baby!® improved their mood, as related to their joint pain.

While Yeahhh Baby!® led to significant improvements in pain and physical function, the placebo treatment also trended towards significance for physical function and WOMAC total (Table 4). The placebo effect on joint pain is well reported within the osteoarthritis literature.²⁶ An appropriate placebo is therefore important in providing a contextual effect. A meta-analysis of osteoarthritis studies found that the effect of topical and intra-articular placebos had a greater effect than oral placebos,²⁷ supported by the noted findings in the present study. Additionally, the placebo effect was higher in studies with smaller number of subjects. With only 20 subjects completing the study involving a topical treatment, it is therefore not surprising that the use of the placebo ointment led to some improvements in the present study. Future studies with a larger sample size may help to mask the placebo effect.

A major limitation of this study was the short period of treatment. Subjects only applied the Yeahhh Baby!® ointment or placebo daily for two weeks. It is unknown how applying the Yeahhh Baby!® ointment over a longer period of time would impact joint pain and physical function. Arthritis Relief Plus,

for example, has been suggested to only provide benefit after three weeks of use.²⁴ Other studies have also employed a longer treatment period,^{20,25} with an extended time possibly needed to fully realize the benefits gained from herbal topical treatments.²⁸ Future studies are needed to determine how continuing the use of Yeahhh Baby!® ointment beyond two weeks may favorably alter joint pain and related measures. Additionally, our study only compared the Yeahhh Baby!® product to a placebo, rather than another pain relief product. Follow-up studies may be focused on a direct comparison between various pain relief products, which may provide subjects with a better understanding of which product might yield the best overall effects. Finally, including a much larger sample of individuals may provide additional insight regarding the effectiveness of treatment.

Conclusion

As compared to a placebo, it appears that Yeahhh Baby!® ointment may provide relief to individuals suffering from joint pain in their knees and/or hips. The Yeahhh Baby!® product may be considered as an alternative treatment to other over-the-counter and off-the-shelf joint pain remedies; however, it is unknown how this product directly compares to these other products in terms of effectiveness, as head-to-head studies would be needed to determine this. This may be the focus of future research, in addition to the inclusion of a larger sample size and a longer period of treatment—all of which should be considered in an attempt to extend these initial findings.

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Author Contributions

RJB was responsible for receipt of funding, study design, study oversight, and manuscript preparation. JP was responsible for data collection, data entry, and manuscript preparation. RM and AS were responsible for coordinating subject recruitment and scheduling, data collection, and data entry. MBS was responsible for data analysis and manuscript preparation. All authors read and approved of the final manuscript.

Declaration of Conflicting Interests

No author declares a specific conflict of interest related to this work. However, in the past three years, in addition to receiving grant funding from Yeahhh Baby!, LLC, RJB has received research funding from the following companies: Liquid IV, USANA Health Sciences, Mannatech, Nuun & Company, CalerieHealth, DSE Healthcare, Zycal Bioceuticals, and Deerland Probiotics and Enzymes. He has served as a consultant to Mannatech, CalerieHealth, and BAT. The sponsor had no role in the execution of the study, or in the interpretation of the study data.

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Ethical Approval

All procedures were approved by the University of Memphis Institutional Review Board for Human Subjects Research (protocol PRO-FY2021-94).

ORCID iD

Richard J. Bloomer  <https://orcid.org/0000-0003-4277-3207>

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