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Assessing the Safety and Efficacy of a Noninvasive Device in the Management of Musculoskeletal Pain Using Low-Level Light Therapy: Double-Blinded, Randomized, Placebo-Controlled, Multicentric Study

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Abstract

Background: Musculoskeletal pain significantly impacts quality of life and daily functioning. Light-based therapies, including those using red and infrared wavelengths, have shown potential in pain management due to their anti-inflammatory and tissue healing properties. CURAPOD, a pain management device developed by Litemed, uses a combination of visible red and infrared light for noninvasive pain relief.

Objective: This study aimed to assess the safety and efficacy of Litemed's pain management device (CURAPOD) in managing acute and chronic musculoskeletal pain at various pain sites, in comparison with a placebo, and to evaluate its efficacy across different skin types.

Methods: In a double-blinded, randomized, placebo-controlled, multicentric study, 240 participants (aged 18 - 60 years) with acute or chronic musculoskeletal pain were enrolled and treated with either the test or control device for 30 minutes. The test device contains 7 LEDs designed to emit a combination of visible red and infrared radiation, while the control device emits visible light of the red spectrum. Pain intensity was subjectively measured at baseline, at 30 minutes after treatment, and at time windows of 8 to 12 hours and 21 to 24 hours after treatment.

Results: A greater number of participants reported a reduction in pain (of up to 60%) in the treatment group than in the placebo group. Repeated measures ANOVA revealed significant effects of time ($F_{3,684}$=282.37; P<.001) and treatment group ($F_{1,228}$=662.12; P<.001), indicating that the relief experienced may be more sustained in the treatment group. No significant effects of pain site ($F_{5,228}$=0.169; P=.97) or skin type ($F_{5,228}$=0.8; P=.55) were observed, suggesting consistent action across anatomical locations and skin types. No significant adverse events were reported.

Conclusions: The device appears to be safe and viable as a nonpharmacological adjunct for managing acute and chronic musculoskeletal pain. Treatment with the device showed short-term pain reduction, with reports of up to 60% pain reduction within 30 minutes of use and sustained self-reported relief in pain for up to 20 hours after treatment. No significant effects of pain sites or skin type on reduction in visual analog scale scores were observed, suggesting broad applicability. However, these results must be interpreted with caution while considering the limitations inherent to the study methodology and short-term follow-up. These findings should be interpreted as evidence of short-term analgesic response rather than definitive clinical effectiveness. Further investigation through rigorously designed randomized controlled trials and longitudinal studies is necessary

to definitively establish the efficacy of the device, the durability of its action, and the potential integration of CURAPOD into pain management strategies.

Trial Registration: Clinical Trials Registry - India CTRI/2022/07/043775; https://tinyurl.com/29cpmj2p

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KEYWORDS

photobiomodulation; pain management device; pain; low-level light therapy; infrared therapy

Introduction

Pain is believed to be the most universally recognized and oldest symptom of ill health for which people seek medical attention. Millions of patients approach medical facilities for pain-related issues, regardless of age or gender [1].

According to the Global Burden of Disease assessment (2019), musculoskeletal conditions are the most prevalent globally, with lower back pain as the leading contributor. An estimated 1.7 billion people are reported to be affected by musculoskeletal conditions [2], with pain associated with these conditions being the most common form of noncancer pain [3].

Pain limits the ability to accomplish daily and social activities, leading to a cascade of psychological problems such as anxiety, depression, sleep disturbances, impaired cognition, lack of focus, and decreased productivity, which presents a significant burden to the health care system and global economy. The International Association for the Study of Pain has been reinforcing the notion that pain should be recognized as a disease and not merely a symptom [4,5].

The most popular and widely accepted approaches to the management of pain are the use of opioid and nonopioid analgesics (nonsteroidal anti-inflammatory drugs and acetaminophen) with adjuvants (anticonvulsants and antidepressants), which could potentially cause undesirable drug interactions, adverse drug reactions, and a multitude of short- and long-term side effects [6].

Opioids have a known propensity to induce drug tolerance; dependence; and, paradoxically, hyperalgesia when used for extended periods. Their potential for drug dependence and abuse is a significant factor that contributes to the global opioid crisis [7,8].

Nonnarcotic analgesics, such as nonsteroidal anti-inflammatory drugs and acetaminophen, are generally safer and more readily available. However, they can still cause side effects, including gastritis; an increased risk of internal bleeding; and, with chronic use, liver and kidney toxicity [9].

The decisional quandary in pain management lies in the choice of interventions for pain relief to improve quality of life [8], which can be addressed by a multimodal pain management plan emphasizing patient education and self-management strategies that are beneficial to reducing dependence on medication and attenuating their side effects [10]. The biopsychosocial model recognizes that pain is a multifaceted problem with biological, psychological, and social factors [11], offering a holistic approach to pain reduction that combines the use of pharmacologic analgesics in conjunction with psychosocial interventions, such as stress reduction; cognitive behavior therapy; and lifestyle changes with physical therapeutic modalities, including acupuncture, cryotherapy, transcutaneous electrical nerve stimulation, heat therapy, and low-level light therapy [6,10,12].

Low-level light therapy, or photobiomodulation, uses nonthermal, nonionizing light therapy to facilitate tissue healing and was discovered by Hungarian physician Endre Mester in 1967 [13]. It has since been researched widely to elucidate that the primary effects of photobiomodulation occur during irradiation and are mediated by cytochrome c oxidase, a chromophore present within the mitochondrial matrix [14]. As an integral part of the electron transport chain, cytochrome c oxidase, when activated, increases the oxygen intake of the cell and the production of adenosine triphosphate, altering the intermembrane potential and regulating reactive oxygen species. Subsequently, a cascade of secondary effects includes regulation of inflammatory cytokines and gene expression to alter signaling pathways and transcription factors [15,16]. Additionally, there is an increase in the availability of nitric oxide, which may be due to the effects on the mitochondria and direct photodissociation, resulting in an increase in blood flow to the tissues [17]. These processes collectively aid in tissue healing and pain relief.

Lasers were initially used to deliver low-power, high-fluence monochromatic light for therapeutic purposes, which led to the term low-level laser therapy. Later, LEDs were found to produce similar effects, leading to the more encompassing photobiomodulation [14]. LEDs do not produce coherent light, unlike their laser counterparts, which help them achieve their therapeutic effect with a lower risk of burns that are usually associated with laser therapy [18]. Litemed's CURAPOD device is a noninvasive, compact, portable device that uses these principles of photobiomodulation to deliver a combination of therapeutic wavelengths of light through LEDs, allowing it to be self-administrable. With little to no side effects, the device aims to provide a safe and effective alternative or complement to traditional pain management practices that often carry documented risks. This study evaluated the effectiveness of CURAPOD therapy for pain relief across various anatomical pain sites among patients with different skin types.

Methods

This was a randomized, double-blinded, multicentric, 2-arm, parallel, placebo-controlled study conducted with a study population of 240 participants.

Ethical Considerations

This study was conducted in accordance with the ethical guidelines of the current version of the Declaration of Helsinki (64th World Medical Association General Assembly, Fortaleza, Brazil, October 2013). The trial was conducted in accordance with the International Conference on Harmonisation guidelines on Good Clinical Practice E6 (R2).

Ethics approval was obtained at each site from its respective institutional ethics committee.

Ethics approval for the final study protocol was obtained prior to study initiation from the following:

- The Institutional Ethics Committee for Biomedical Research, Apollo Hospital, Chennai (AMH-C-S-027/05 - 22 approved on May 20, 2022)
- The Sri Ramachandra Institutional Ethics Committee, Chennai (IEC/22/APR/171/32 approved on August 3, 2022)
- The Nizam's Institute of Medical Sciences Institutional Ethics Committee, Hyderabad (EC/NIMS/3045/2022 approved on September 8, 2022)
- The KIMS Ethics Committee, Hyderabad (KIMS/EC/2022/95 - 03 approved on September 9, 2022)

All participating centers initiated the study only after receiving the respective ethics committee approvals.

Written informed consent was obtained from all participants prior to the performance of any study-related procedures, following which only anonymized, deidentified participant data were used for the purpose of the study, and appropriate measures were taken to ensure participant confidentiality throughout the study. Participants were not compensated for their role in the study in compliance with Indian Council of Medical Research's ethical guidelines.

Study Objectives and Design

Our objective was to evaluate the safety and efficacy of CURAPOD as an adjunct for managing acute and chronic pain arising from various sites in the body. Additionally, the efficacy of CURAPOD across different skin types defined by the Fitzpatrick scale (I-VI), which classifies skin by UV response, was assessed, along with the time to recurrence of pain following a single treatment session [19].

The study was conducted at 4 tertiary care hospitals across South India over a 3-month period, during which individual patient participation lasted 1 visit, with telephonic follow-up at 8 to 12 hours and 21 to 24 hours after treatment. A sample size of 240 participants, randomized in a 1:1 allocation ratio, with 120 (50%) participants assigned to each treatment group, was calculated assuming a minimum mean difference of 1 point in the change from baseline visual analog scale (VAS) score between the test and placebo groups over 1 day, an assumed SD of 2 points, 85% statistical power, a 2-sided α level of .05, and an anticipated dropout rate of 20%.

Adults aged 18 to 60 years were screened and enrolled based on a clinical diagnosis of either acute or chronic pain of musculoskeletal origin, as determined by the site investigator (based on medical history and physical examination), with an intensity on the VAS ranging from 4 to 7 on a scale of 0 to 10 [20].

For diagnosis, acute pain was defined as pain of short duration, typically lasting less than 3 months and associated with a healing tissue injury. Chronic pain was characterized by its persistence beyond the normal healing period, generally extending beyond 3 months. Patients with pain localized to the neck, shoulder, back, arm, knee, and leg were considered, and they were required to abstain from seeking any other pain relief treatments during the study.

Patients with psychosomatic pain conditions, deep vein thrombosis, varicose veins, gout, ganglionic cysts, bone fractures, cervical spondylosis, and postoperative surgical pain were excluded from the study. Patients with pain intensity greater than 7 on the VAS scale were also excluded to minimize patient discomfort. Additionally, those with unhealed injuries that resulted in a break in the continuity of the skin at the pain site were also excluded, as it may lead to complexities in device application.

Anyone with a known drug allergy to aceclofenac and diclofenac (planned rescue medication for the study) was also excluded, as were those who had received any other pain management treatment 24 hours prior to their enrollment.

Randomization and Blinding

The study population was divided into 2 arms of 120 participants each, one receiving treatment with the experimental intervention and the other with a placebo. SAS software (version 9.4; SAS Institute Inc) was used to allot participants into their treatment groups in a 1:1 ratio using stratified block randomization, with the 6 pain sites forming the strata. Knowledge of randomization was restricted to those responsible for generating it. A sealed copy of the randomization scheme and code was retained at the study site. It could be accessed in case of emergency unblinding to verify the treatment identity of individual subjects.

The investigational product and placebo were labeled and packaged at the manufacturing site to ensure blinding. An independent dispenser, who was not involved in any other study-related activities, was responsible for handling the investigational products at the study site. The treatment phase was conducted in a double-blinded manner. Although a formal blinding survey was not conducted, all parties, including investigators, participants, site staff, the Contract Research Organization team, study monitors, laboratory personnel, sponsor representatives involved in study oversight, and other designated individuals involved in the conduct of the study, remained blinded to treatment assignments until the study blind was broken following database lock.

Test Device

Litemed's pain management device consists of a pair of disk-shaped devices with adhesive patches designed for application on the skin and an orthopedic band meant to secure the devices in place.

Each device has a diameter of 48.6 mm and an exposure area of 18.54 cm^2, containing 7 LEDs, of which 3 LEDs emit light in the visible red spectrum (660 nm) and 4 LEDs emit light in

the infrared spectrum (850 nm). CURAPOD is meant to be used as a pair, doubling the number of LEDs and the area exposed.

The fully charged device is placed on the identified site of pain with the help of the adhesive patches provided and secured in place by wrapping the orthopedic band. It has an autoshutdown mechanism at 30 minutes from activation, following which the orthopedic band is removed and the adhesive is slowly peeled from the skin.

Placebo

The placebo, identical in form and use to the experimental device, contains visible LEDs that emit visible red light of 0.8 mW irradiance, mimicking the visual experience of the active device without the infrared component.

Both the active and sham devices emitted visible red light to maintain visual similarity during treatment. The active device additionally delivered infrared wavelengths and a higher total energy dose, which were not visually perceptible. A formal assessment of blinding success using postintervention questionnaires was not conducted; therefore, inadvertent unblinding of participants or study personnel cannot be excluded.

Each participant was involved in the study for 1 day, which included 1 hospital visit and 2 telephone calls across 2 time windows. Prospective participants were identified in the outpatient department and inpatient department if they presented with musculoskeletal pain and were screened for eligibility after obtaining informed consent and collecting relevant demographic and medical history data. Treatment was administered according to the randomization schedule after noting the baseline pain intensity, which was measured using the VAS according to the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) guidelines as the responsive primary outcome for acute pain relief, and skin type was assessed using the Fitzpatrick skin type classification [20]. Posttreatment measurements were made 30 minutes after a single session to provide a rest period during which the participants were closely monitored for any adverse events. Participants were handed patient diaries and prescribed rescue medication with relevant instructions, and the follow-up was conducted at the 8- to 12-hour and 21‐ to 24-hour time windows.

Statistical Analysis

The statistical analysis was computed using SAS software (version 9.4) and used repeated measures ANOVA (RM-ANOVA). Continuous variables were summarized with mean, SD, median, minimum, maximum, and number of nonmissing observations for each treatment group. Categorical variables were summarized by counts and the percentage of participants in corresponding categories. Missing data were minimal and handled using complete case analysis.

An RM-ANOVA was used to assess the varying effectiveness of therapy in terms of changes in VAS scores before and after treatment in both groups at set time points. The analysis focused on the difference in changes in pain scores over time between treatment and placebo groups on various pain sites and skin types.

The primary analysis was performed on the intent-to-treat population and the per-protocol population to assess the difference in treatment efficacy, as measured by the change in VAS score from baseline, between Litemed's pain management device and the control device.

The secondary analysis was also performed on the intent-to-treat and per-protocol populations. Proportions and percentages were used to compare pain relapse between the CURAPOD and control devices. The chi-square test was used to analyze the percentage of patients whose pain relapse occurred between 8 to 12 hours and 21 to 24 hours.

Analysis of covariance was performed as a supportive analysis to compare posttreatment pain intensity between treatment groups at 30 minutes. The posttreatment VAS score was treated as the dependent variable, and treatment group and pain site were included as fixed effects, with baseline VAS score as a covariate. Safety evaluation was performed on all randomized patients.

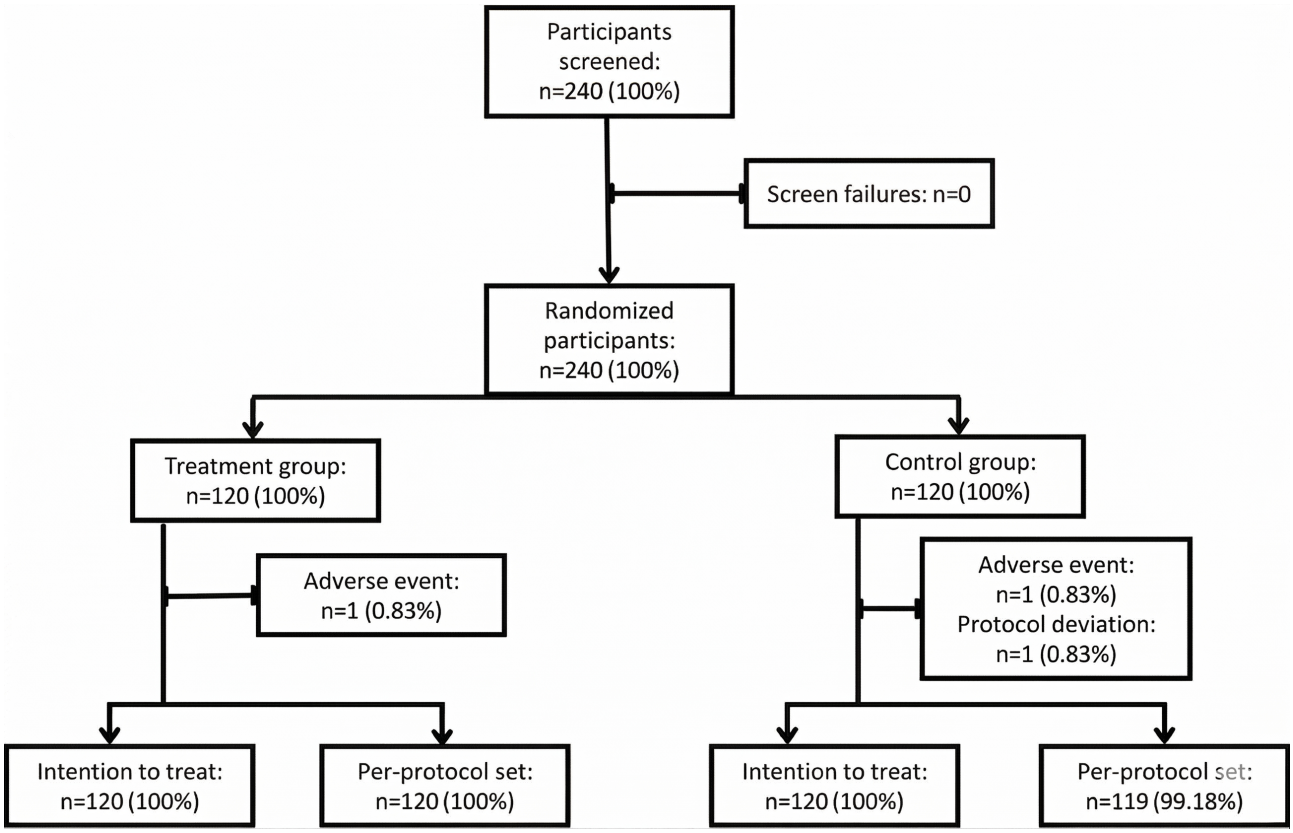
A P value of <.05 was considered statistically significant for all analyses.

Results

Overview

In total, 240 patients were enrolled in the study, of whom 239 (99.5%) completed the study successfully, and 1 protocol deviation was recorded (Figure 1). In total, 10 (4.2%) participants reported receiving 1 dose of rescue medication during the follow-up period; of these, 8 (3.3%) were from the placebo group and 2 (0.8%) were from the treatment group.

Figure 1. Study flow diagram.



Safety and Tolerability

In total, 2 adverse events were reported (1 in each group). One participant in the placebo arm reported mild irritation at the site of application that resolved spontaneously, and 1 participant from the treatment arm experienced itching and redness at the device application site approximately 15 minutes after application, which resolved after intervention by the study investigator. No serious adverse events or discontinuations due to adverse effects occurred.

Baseline Characteristics

The 2 study groups were comparable at baseline, with no statistically significant differences in demographic and clinical characteristics as summarized in Table 1.

Table . Demographic characteristics of study populations at baseline.

Demographic characteristics	Treatment group (n=120), n (%)	Control group (n=120), n (%)	*P* value
Age (years), mean (SD)	38.3 (12.16)	36.5 (12.54)	.25
Age group (years), n (%)			.36
18 - 30	38 (31.7)	50 (41.7)	
31 - 40	26 (21.7)	21 (17.5)	
41 - 50	29 (24.2)	29 (24.2)	
51 - 60	27 (22.5)	20 (16.7)	
Sex, n (%)			.90
Female	60 (50.0)	61 (50.8)	
Male	60 (50.0)	59 (49.2)	
Pain condition, n (%)			.61
Acute	61 (50.8)	65 (54.2)	
Chronic	59 (49.2)	55 (45.8)	
Skin type, n (%)			.98
Type 1	10 (8.3)	12 (10.0)	
Type 2	16 (13.3)	17 (14.2)	
Type 3	23 (19.2)	19 (15.8)	
Type 4	27 (22.5)	29 (24.2)	
Type 5	27 (22.5)	25 (20.83)	
Type 6	17 (14.2)	18 (15.0)	

Descriptive Statistics and Efficacy Outcomes

At baseline, the mean VAS pain score was similar between groups: 5.78 (SD 1.09) in the treatment group and 5.58 (SD 0.95) in the control group. After treatment, greater reductions in pain were observed in the treatment group across all time points evaluated (30 minutes, 8 - 12 hours, and 21 - 24 hours) compared with the control group, as shown in Table 2.

Table . Mean VAS[a] scores, absolute change from baseline, and percentage change for the treatment (n=120) and control (n=120) groups at baseline, 30 minutes, 8–12 hours, and 21–24 hours after treatment. Baseline scores were similar between groups. The treatment group showed greater reductions in pain at all post-treatment time points compared to the control group.

Time point	VAS score, mean (SD)		Change in VAS score, mean (SD)		Percentage change in VAS score, mean (SD)	
	Treatment group (n=120)	Control group (n=120)	Treatment group (n=120)	Control group (n=120)	Treatment group (n=120)	Control group (n=120)
Baseline VAS score	5.78 (1.086)	5.58 (0.949)	—[b]	—	—	—
30 minutes after treatment	2.17 (1.155)	5.38 (1.063)	3.62 (0.963)	0.20 (0.544)	63.64 (16.640)	3.59 (9.439)
8 to 12 hours after treatment	2.06 (1.318)	5.53 (0.987)	3.73 (1.283)	0.06 (0.325)	65.02 (21.216)	1.02 (5.621)
21 to 24 hours after treatment	3.03 (2.037)	5.38 (1.124)	2.75 (2.059)	0.20 (0.740)	47.40 (34.044)	3.31 (12.317)

[a]VAS: visual analog scale.

[b]Not applicable.

Relapses of Pain After Treatment

Relapse of pain was assessed among the participants who had reported a reduction in pain 30 minutes after treatment, which included 98.3% of (118/120) participants from the treatment group and 14.2% (17/120) of participants from the placebo group. The percentage of relapse of pain is summarized in Figure 2 and Table 3, showing a higher percentage of relapse in the control group.

Figure 2. Comparison of mean percentage pain relief of various pain sites across skin types.

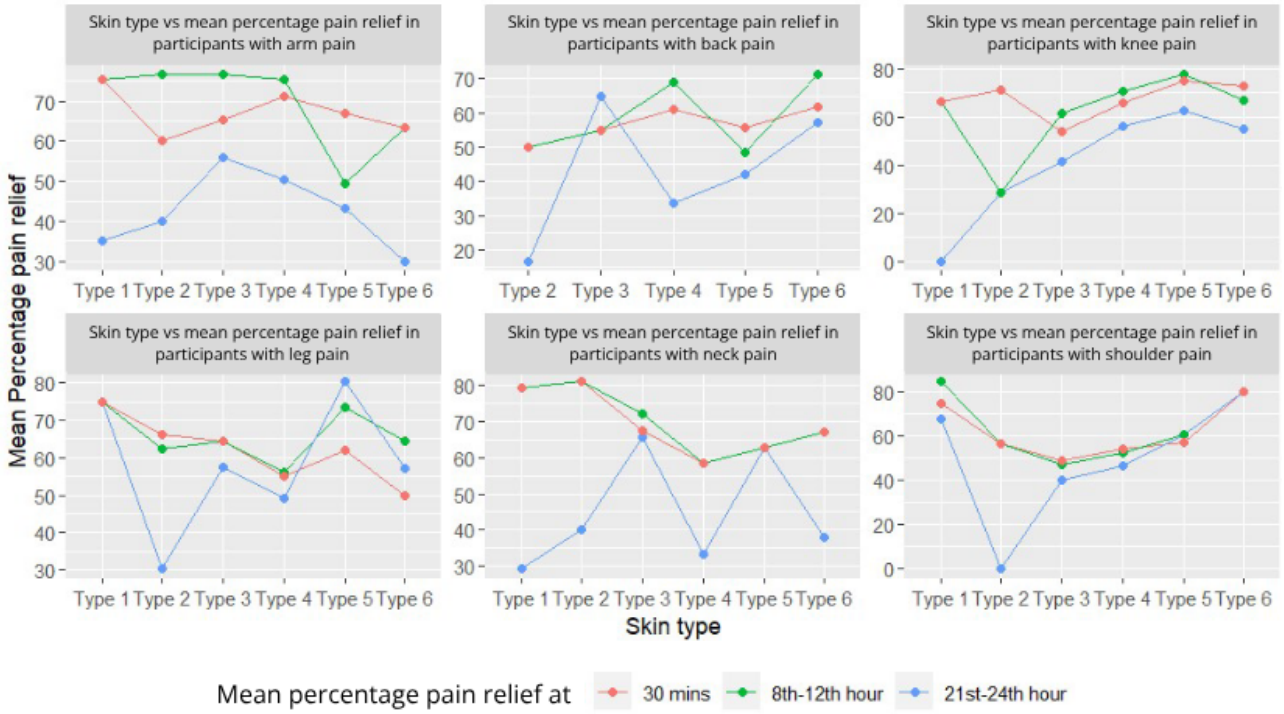


Table . Summary of the proportion of participants with pain relapse by treatment arm—intention-to-treat population.

Variable	Treatment group (n=118), n (%)	Control group (n=17), n (%)	*P* value[a]
Telephonic call (status review at 8-12 hours)			<.001
No relapse of pain	110 (91.67)	4 (23.53)	
Pain relapsed	10 (8.33)	13 (76.47)	
Telephonic call (status review at 21-24 hours)			<.001
No relapse of pain	67 (56.78)	1 (5.88)	
Pain relapsed	51 (43.22)	16 (94.12)	

[a]*P* values were determined using the χ^2 test.

RM-ANOVA Analysis

Overview

RM-ANOVA was used to evaluate the effect of treatment on VAS scores, controlling for baseline values, pain sites, and skin types.

Table 4 summarizes the descriptive statistics of the change in VAS score, categorized in terms of anatomical site of pain and skin type.

Table . Descriptive statistics of visual analog scale (VAS) score changes by pain site and skin type in the treatment group.

Subgroup	Control			Treatment		
	Values, n (%)	Mean baseline VAS (SD)	Mean change (SD)	Values, n (%)	Mean baseline VAS (SD)	Mean change (SD)
Pain site						
Arm	20 (16.6)	5.80 (0.83)	0.05 (0.22)	20 (16.6)	5.50 (1.00)	3.65 (0.88)
Back	20 (16.6)	5.45 (0.94)	0.20 (0.70)	20 (16.6)	6.00 (1.08)	3.40 (0.68)
Knee	20 (16.6)	5.50 (1.15)	0.25 (0.55)	20 (16.6)	5.55 (1.15)	3.70 (0.98)
Leg	20 (16.6)	5.65 (1.09)	0.20 (0.52)	20 (16.6)	5.80 (1.24)	3.55 (1.10)
Neck	20 (16.6)	5.45 (0.83)	0.20 (0.70)	20 (16.6)	5.85 (1.09)	3.95 (1.10)
Shoulder	20 (16.6)	5.65 (0.88)	0.30 (0.47)	20 (16.6)	6.00 (0.97)	3.45 (1.00)
Skin type						
Type 1	12 (10)	5.58 (0.67)	0.33 (0.89)	10 (8.3)	5.50 (1.18)	4.10 (0.99)
Type 2	17 (14.1)	5.82 (1.01)	0.12 (0.49)	16 (13.3)	5.81 (0.91)	3.75 (1.24)
Type 3	19 (15.8)	6.00 (1.04)	3.48 (0.79)	23 (19.1)	5.84 (1.01)	0.26 (0.45)
Type 4	29 (24.1)	5.81 (1.08)	3.52 (0.98)	27 (22.5)	5.24 (1.02)	0.21 (0.49)
Type 5	25 (20.8)	5.85 (1.13)	3.67 (1.04)	27 (22.5)	5.44 (0.82)	0.12 (0.33)
Type 6 (skin)	18 (15)	5.47 (1.23)	3.47 (0.72)	17 (14.1)	5.83 (0.92)	0.22 (0.73)

Effectiveness of Litemed's CURAPOD on Change in VAS Score and Pain Site

RM-ANOVA assessing the effects of time, treatment group, and pain site on the change in VAS scores revealed significant main effects of time ($F_{3,684}$=282.37; P<.001) and treatment group ($F_{1,228}$=662.12; P<.001), indicating that pain scores changed over time and were significantly lower in the treatment group compared with the control group. However, the effect of pain site was not significant ($F_{5,228}$=0.169; P=.97), suggesting that the efficacy of the device was consistent across different anatomical locations.

Effectiveness of Litemed's CURAPOD in Pain Relief Among Different Skin Types

All participants were divided into skin types per the Fitzpatrick skin scale at baseline [19]. RM-ANOVA based on the classified skin type revealed no significant effects ($F_{5,228}$=0.8; P=.55) on change in VAS scores, suggesting that the device is effective across all skin types.

Effectiveness of Litemed's CURAPOD in Pain Relief Among Different Pain Conditions

RM-ANOVA based on pain conditions revealed no significant effects on change in VAS score ($F_{1,236}$=1.718; P=.19), suggesting that the duration of pain (acute or chronic) does not affect the efficacy of the device.

Effect Size Calculation

Effect size analysis comparing the treatment group with the control group and the incidence of pain relapse are summarized in Tables 5 and 6. Effect size analyses demonstrate that the treatment group demonstrated a greater magnitude of pain reduction and relapse prevention. Changes in VAS scores appear to favor the treatment group at all time points, with mean differences of 3.42 (SD 1.12; 95% CI 3.22 - 3.62; Cohen d=4.33) at 30 minutes, 3.67 (SD 1.46; 95% CI 3.41 - 3.93; Cohen d=3.40) at 8 to 12 hours, and 2.55 (SD 1.65; 95% CI 2.18 - 2.92; Cohen d=1.65) at 21 to 24 hours. Correspondingly, pain relapse was lower in the treatment group, with 91.7% remaining relapse free at 8 to 12 hours vs 3.3% in the control group (ϕ=0.72) and 55.8% vs 0.8% at 21 to 24 hours (ϕ=0.56).

Table . Treatment-control effect sizes with 95% CIs.

Time point	Mean difference[a] (SD) ΔVAS[b]	95% CI	Cohen d
30 minutes	3.42 (1.12)	3.22 - 3.62	4.33
8 to 12 hours	3.67 (1.46)	3.41 - 3.93	3.40
21 to 24 hours	2.55 (2.07)	2.18 - 2.92	1.65

[a]Mean difference is the difference between the treatment and control groups in mean change from baseline VAS score at the specified time point.

[b]VAS: visual analog scale.

Table . Relapse outcomes (chi-square test).

Time point	No relapse treatment (n=120), n (%)	No relapse control (n=120), n (%)	ϕ
8 to 12 hours	110 (91.7)	4 (3.3)	0.72
21 to 24 hours	67 (55.8)	1 (0.8)	0.56

Sensitivity Analysis

Sensitivity analysis was performed using analysis of covariance, adjusting for baseline VAS score and pain site. A statistically significant effect of treatment was observed on posttreatment VAS scores at 30 minutes ($F_{1,232}$=1180.88; P<.0001). The effect of pain site was not statistically significant ($F_{5,232}$=0.86; P=.51), consistent in direction and magnitude with the primary analysis.

Discussion

Principal Findings

This study aimed to evaluate the safety and efficacy of the CURAPOD device, which uses specific wavelengths of light applied to the skin to promote tissue healing and alleviate pain in both acute and chronic conditions.

Participants in the treatment group reported significant reductions in pain scores as early as 30 minutes after treatment, with sustained effects observed at 8 to 12 hours and 21 to 24 hours. The magnitude of change in VAS scores and percentage reduction in pain were consistently higher in the CURAPOD group compared with controls at all time points assessed. The analysis of covariance findings further support the observed treatment effects, demonstrating that the reduction in pain at 30 minutes remained statistically significant after adjustment for baseline pain severity and pain site. However, the magnitude of the observed effect sizes should be interpreted cautiously, as outcomes were assessed immediately following a single treatment session using a highly sensitive and subjective pain scale (VAS), conditions that may accentuate short-term treatment contrasts.

Notably, the frequency of reporting a relapse in pain was significantly lower in the treatment group, suggesting a more durable therapeutic effect. However, relapse rates were assessed only among participants who experienced an initial reduction in pain, leading to a substantial imbalance in denominators (17 in the placebo group vs 118 in the treatment group), possibly distorting the analysis of pain recurrence between the 2 groups. Additionally, as no formal blinding assessment was performed, inadvertent blinding may have occurred, resulting in the vast differences in relapse rates between the 2 groups.

As the depth of light penetration is influenced by both wavelength and the melanin concentration in the skin, participants were categorized using the Fitzpatrick scale to evaluate the device's efficacy across different skin types [21]. The results showed that participants in the treatment group reported a significant reduction in pain after treatment, irrespective of their skin type, suggesting that CURAPOD's effect is consistent across diverse skin tones. Other LED-based photobiomodulation devices have also shown promise in clinical studies for conditions such as knee pain and chronic lower back pain, with reported benefits including reduced pain intensity and decreased reliance on analgesic medications [22-26]. Our findings position Litemed's CURAPOD as a viable adjunct to pain management, delivering pain relief within 30 minutes of first use across diverse pain sites and skin types. The relatively small sample sizes of the subgroups (ie, skin types and pain site) and the geographical restriction of study sites to South India may affect the precision of subgroup analysis and must be taken into consideration when interpreting the generalizability of our findings.

This clinical study demonstrated the safety and efficacy of CURAPOD in this study population within the constraints of a short-term randomized trial, showing reduced pain and a lower proportion of relapse within 24 hours compared with the control device. However, this does not translate to clinical efficacy of the device, and our findings should be considered in view of the several limitations of this study. The protocol limited treatment to one 30-minute session, which is insufficient to establish sustained or cumulative long-term efficacy across various pain conditions. RM-ANOVA showed time effects but was limited due to the nature and duration of follow-up, which lasted a maximum of 24 hours. Telephonic follow-up renders the outcome vulnerable to recall bias, nonresponse (as seen with 1 participant who was lost to follow-up), or interviewer influence. Most importantly, efficacy assessments were based on self-reported VAS scores. Our single-session study design precluded the use of accompanying objective measures such as range of motion, functional activity levels, biomarker analysis (eg, inflammatory cytokines), or neuroimaging such as functional magnetic resonance imaging to monitor and validate pain reduction. Reliance on subjective measures alone may have contributed to information bias and potential placebo effects that were amplified by the device's heat sensation. An official blinding validation was not conducted; while the treatment and placebo devices both emitted visible red light for visual similarity, sensory matching was not carried out, which may have inadvertently led to partial unblinding. The sensory stimulation from the active device may cause counter-stimulation, which can distract from pain independently of the therapeutic effects of the device and is likely to have contributed to the large effect size observed in our study. These limitations need to be taken into consideration while planning future studies with long-term follow-ups to include objective measures of pain and blinding validation to accurately assess the efficacy of the device in pain management.

Conclusions

Within the constraints of this study, the CURAPOD device was associated with greater short-term reductions in self-reported musculoskeletal pain compared with sham treatment. Litemed's CURAPOD device was associated with pain reduction (up to 60% within 30 minutes) for acute and chronic musculoskeletal pain across various sites and Fitzpatrick skin types, as observed

in this single-session, double-blind randomized controlled trial. Participants reported relief sustained up to 24 hours, with lower relapse rates compared with placebo, along with an excellent safety profile and no serious adverse events. However, these findings must be interpreted considering study limitations, including short-term follow-up, reliance on subjective VAS measures, and regional sampling, which preclude conclusions about long-term efficacy or broad generalizability. Future multisession trials with objective outcomes in diverse populations are required to further validate CURAPOD's therapeutic potential as an adjunct for acute pain management in clinical practice.

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Data Availability

Datasets generated and analyzed during this study are not publicly available to maintain participant privacy but are available from the corresponding author on reasonable request.

Authors' Contributions

SPM contributed to the conceptualization and overall study design and served as the corresponding author. SLA, SAN, CP, ALA, AKBK, SM, and RS contributed to the conceptualization and conduct of the study and provided oversight of data collection. VKP contributed to study design and oversight. VS participated in study design, performed data analysis, and contributed to the interpretation of results. All authors reviewed and approved the final manuscript.

Conflicts of Interest

SPM and VKP are the owner and an employee, respectively, of Litemed India Pvt Ltd. Litemed India Pvt Ltd is the manufacturer of the CURAPOD device. This represents a potential conflict of interest in the interpretation of the results. The authors were involved in study design and provided oversight during study execution but had no role in participant selection, study conduct, data collection, analysis, or interpretation of results. All other authors declare no other conflicts of interest.

Checklist 1
CONSORT-EHEALTH checklist.
[PDF File, 263 KB - biomedeng_v11i1e87566_app1.pdf]

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Abbreviations

IMMPACT: Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials
RM-ANOVA: repeated measures ANOVA
VAS: visual analog scale

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Remote Monitoring of Bioelectrical Impedance in Patients With Breast Cancer–Related Lymphedema: 1-Year Pilot Longitudinal Study

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Abstract

Background: Breast cancer–related lymphedema (BCRL) is a chronic complication that impairs quality of life through persistent fluid accumulation. While clinical guidelines recommend longitudinal surveillance, implementation is often limited by the logistical challenges of frequent in-clinic visits. Bioelectrical impedance analysis (BIA), specifically the segmental extracellular water–to–total body water (ECW/TBW) ratio, offers a noninvasive method for tracking fluid status. However, the technical agreement between in-clinic and patient-led home-based BIA systems, as well as the feasibility of long-term self-monitoring in real-world settings, remains to be fully established.

Objective: Our primary objective was to evaluate the agreement between in-clinic and home-based BIA systems for key body composition and fluid-related parameters. Our secondary objective was to characterize longitudinal fluid patterns and diurnal variations in ECW/TBW ratios to assess the feasibility of home-based monitoring.

Methods: This prospective, patient-driven, 12-month observational study enrolled breast cancer survivors at risk for lymphedema. Agreement between the in-clinic BIA system (InBody 770) and the home-based device (BWA ON) was assessed using Bland-Altman analysis, intraclass correlation coefficients (ICCs), and the Lin concordance correlation coefficient (CCC). Longitudinal home-based ECW/TBW measurements were analyzed using linear mixed-effects models to evaluate diurnal differences (before-noon vs after-noon) across groups defined by limb dominance and BCRL status (International Society of Lymphology [ISL] stage 0 vs stage 1).

Results: Over 12 months, ECW/TBW ratios measured by the home-based device demonstrated strong agreement with in-clinic measurements, showing minimal bias and high ICC/CCC values. Longitudinal analysis revealed that ECW/TBW changes did not follow uniform patterns within ISL stage categories, showing substantial physiological heterogeneity even among clinically stable groups. Diurnal analysis identified a small but statistically significant decrease in ECW/TBW ratios in the afternoon (P<.001). The magnitude of this decrease differed by limb dominance and BCRL status, with the most pronounced reduction observed in participants whose dominant arm was affected and who had a history of stage 1 lymphedema. ECW/TBW variability was driven more by within-individual factors (eg, measurement timing) than by between-individual differences.

Conclusions: Home-based segmental bioimpedance provides reliable longitudinal data and reveals granular fluid patterns not captured by conventional ISL staging alone. The significant impact of diurnal variation, particularly in relation to limb dominance, underscores the need for standardizing measurement protocols. Standardizing home-based measurements to a fixed monitoring

time can minimize physiological noise and enhance the interpretability of long-term self-monitoring strategies for breast cancer survivors.

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KEYWORDS

bioelectrical impedance analysis; breast cancer-related lymphedema; ECW/TBW ratio; longitudinal study; patient-led monitoring; diurnal variation

Introduction

Breast cancer is the most commonly diagnosed cancer and the leading cause of cancer-related death in women, followed by lung cancer [1]. Breast cancer mortality is decreasing due to improved diagnostics and treatments. As survival is increased, the long-term sequelae of treatment and impaired quality of life become relevant [2]. Because of improvements in cancer diagnostic modalities, surgical technology, and targeted treatment, breast cancer mortality has been continuously decreasing during the past few decades, and the number of long-term cancer survivors is consequently continuing to increase. However, many breast cancer survivors develop negative sequelae, such as lymphedema, neuropathy, shoulder morbidity, depression, and anxiety [3].

Lymphedema is a chronic condition characterized by abnormal lymph fluid accumulation and is broadly classified as primary or secondary. Primary lymphedema results from developmental abnormalities of the lymphatic system, whereas secondary lymphedema is caused by acquired damage to lymphatic vessels due to trauma, tumor, surgery, infection, or cancer treatment. In transitional countries, secondary lymphedema is most commonly associated with infectious or parasitic diseases affecting lymphatic channels, while in high-income countries it most frequently occurs following lymph node dissection for cancer management. Clinically, lymphedema is characterized by chronic swelling, localized pain, atrophic skin changes, localized fluid imbalance, and recurrent secondary infections, regardless of etiology. Beyond physical symptoms, one of the most debilitating aspects of lymphedema is visible limb disfigurement, which is strongly associated with psychological morbidity and impaired quality of life [4,5].

Breast cancer–related lymphedema (BCRL) is the most common form of secondary lymphedema, reflecting the high global prevalence of breast cancer among women. BCRL affects approximately 3‐5 million individuals worldwide, with an estimated 20,000 new cases annually in the United States, and reported incident rates range widely from 2% to 77% depending on the extent of local-regional and systemic therapies [6]. BCRL arises from disruption of the lymphatic system during breast cancer treatment, particularly following axillary lymph node dissection (ALND), radiation therapy, and systemic chemotherapy [1,2,7-9]. Historically, BCRL incidence has reached 20%‐40% in patients undergoing ALND [5-11]. Established risk factors include the number of lymph nodes removed, exposure to chemotherapy and radiation, elevated BMI, and patient comorbidities [1,3,5,12,13]. Given the high incidence and chronic nature of BCRL, continuous and accessible monitoring of limb fluid status is essential for maintaining the quality of life in this growing survivor population.

Early lymphedema, defined as subclinical disease or stage 1 according to the International Society of Lymphology (ISL) classification, has been shown to be potentially reversible when identified and managed promptly [3,14-17]. In contrast, progression to stage II or III is associated with chronic tissue changes, including fibrosis, rendering the condition reducible but not reversible and less responsive to intervention [7,8]. Accordingly, early identification of BCRL is widely regarded as a critical determinant of long-term outcomes.

Major oncology, survivorship, rehabilitation, and lymphology societies consistently recognized BCRL as a common and potentially lifelong complication resulting from lymphatic system damage following breast cancer treatment, particularly after axillary lymph node surgery [6,8]. The National Comprehensive Cancer Network's breast cancer and survivorship guidelines emphasize that longitudinal surveillance and individualized baseline assessments are essential for optimal LE management and recommend pretreatment bilateral limb measurements to establish an individualized baseline in patients with treatment-related or personal risk factors [16,18,19]. These guidelines further note that while BCRL most commonly develops within the first 3 years after treatment, it may occur at any point during survivorship, and that early-stage disease (stages 0‐1) is potentially reversible, whereas later-stage disease is not [8].

In parallel, the American Society of Clinical Oncology and the American Cancer Society highlight the importance of survivor education focused on risk reduction and recommend prompt referral for patients presenting with symptoms or clinical signs suggestive of lymphedema [5]. Rehabilitation- and lymphology-focused organizations further advocate for objective surveillance strategies, with the American Physical Therapy Association recommending the use of bioimpedance analysis to detect subclinical or early-stage lymphedema [7], and the Australasian Lymphology Association advising routine preoperative assessment using limb circumference measurements and/or bioimpedance spectroscopy, followed by risk-adapted longitudinal monitoring [10]. Similarly, the British Lymphology Society underscores the need for structured patient education prior to cancer treatment, clear referral pathways, and access to designated health care professionals to facilitate early intervention and psychosocial support [9]. Collectively, these recommendations support a proactive and standardized approach to BCRL management that integrates baseline assessment, ongoing surveillance, patient education, and timely referral to specialized lymphedema services.

Despite these consensus recommendations, diagnosing preclinical or subclinical lymphedema remains challenging and requires baseline assessment and surveillance at standardized intervals [9,14-17]. Clinically, BCRL has been defined as a ≥2-cm increase in limb circumference, a ≥200-mL increase in limb volume, or a 5% - 10% change in limb volume compared to the unaffected arm [9-13]. However, there is no single diagnostic criterion with high sensitivity and specificity for lymphedema [8]. Volume-based methods, including tape measurement, water displacement, and perometry, do not differentiate among bone, muscle, fat, and lymphatic or extracellular fluid and are therefore limited in their ability to capture dynamic or transient fluid fluctuations occurring between clinical visits [20,21].

Although physical examination and clinical history remain central to diagnosis, early swelling may be transient; one study reported that approximately one-third of initial swelling episodes resolve spontaneously, further complicating early identification [22]. Given that effective intervention is most successful in early stages, accurate and timely detection of subclinical disease is essential to prevent progression [23].

Bioimpedance techniques provide a fast, noninvasive approach to assessing body water distribution by applying electrical currents at multiple frequencies [3]. At low frequencies, electrical current is restricted to the extracellular compartment and inversely reflects extracellular water (ECW), whereas at higher frequencies it traverses cell membranes, allowing estimation of total body water (TBW) [3]. Because lymphedema is fundamentally characterized by ECW accumulation, bioimpedance is particularly well suited for its detection [4,14,24-29]. Deviations from an individual's baseline bioimpedance values may indicate subclinical lymphedema, providing objective quantification of subtle fluid status that may not be captured by volume-based methods alone, thereby supporting more granular longitudinal tracking [4,14,24-28,30].

Segmental bioelectrical impedance analysis (BIA) further enhances clinical utility by dividing the body into five segments (both arms, both legs, and the trunk) and simultaneously measuring impedance in each segment [31-34]. Segmental ECW/TBW ratios are used to assess fluid imbalance, with values between 0.360 and 0.390 considered physiologically normal and values of >0.390 suggestive of abnormal ECW accumulation [31,35,36]. Because each limb is referenced to its own TBW rather than a contralateral comparison, this approach allows assessment of both unilateral and bilateral lymphedema, objective quantification of limb fluid status, and longitudinal monitoring of treatment response [31-34].

Accordingly, this study was designed as a prospective, patient-driven, real-world observational study reflecting routine clinical practice. In standard post–breast cancer care, lymphedema surveillance and preventive management are typically conducted in rehabilitation medicine clinics at approximately 3-month intervals. While these scheduled, hospital-based assessments provide structured clinical oversight, they are limited in their ability to capture dynamic changes occurring in patients' daily lives between visits.

To address this gap, this study aimed to evaluate how daily, home-based bioelectrical impedance measurements, obtained under real-world conditions, reflect physiological fluid trends. By prospectively collecting patient-generated data, this study sought to characterize the consistency of home-based BIA and analyze how diurnal and behavioral variability influence these metrics. This approach aims to provide evidence for the feasibility of home-based monitoring as a reliable, guideline-concordant strategy that complements periodic in-clinic assessments by providing high-frequency, longitudinal data.

Methods

Participants

This study was a multicenter study conducted across four tertiary hospitals. This involved five in-person clinic visits (baseline, 3, 6, 9, and 12 months) and daily home-based body composition measurements over 1 year. Eligible participants were adult patients (aged 18 years or older) who underwent breast cancer surgery an axillary lymph node dissection or sentinel lymph node biopsy and were therefore considered at risk of developing lymphedema to monitor longitudinal fluid changes. Prophylactic mastectomy and reconstruction were permitted. Participants were excluded if they had a bilateral cancer diagnosis, were pregnant, had an infection (ie, cellulitis), or had an implanted electrical medical device (ie, cardiac pacemaker). The participants were in the self-care phase of treatment. Enrollment took place between February 2023 and July 2024 at four institutions: the REHAB Hospital of the Pacific (Honolulu, Hawai'i), Shirley Ryan AbilityLab (Chicago, Illinois), One Oncology Tennessee (Nashville, Tennessee), and the University of Minnesota (Minneapolis, Minnesota). Recruitment was planned to be evenly distributed across the four regions; however, the number of enrolled participants varied by site during the recruitment period (see Figure 1).

Figure 1. Participant flow and longitudinal monitoring protocol. Participants were enrolled from four institutions over a 29-month period, with each individual followed for a 12-month monitoring period. Baseline in-clinic assessments included site-specific clinical data and bioelectrical impedance analysis (BIA) measurements to establish individual baselines. After receiving standardized training, participants performed patient-led BIA measurements at home, complemented by in-clinic follow-up visits every 3 months for continuous lymphedema surveillance. ALND: axillary lymph node dissection; BC: Breast cancer; DASH: Disabilities of the Arm, Shoulder, and Hand; ISL: International Society of Lymphology; LE: lymphedema; LLIS: Lymphedema Life Impact Scale; OOC: One Oncology Center; REHAB: REHAB Hospital of the Pacific; ROM: range of motion; SLNB: sentinel lymph node biopsy; SRLAB: Shirly Ryan Laboratory; TVM: tape volume measurement; UMN: University of Minnesota.

Ethical Considerations

This prospective, patient-driven, real-world observational study was reviewed and approved by the institutional review boards of all participating sites. Ethical approvals were obtained from the University of Hawai'i Institutional Review Board (REHAB Hospital of the Pacific; IRB No. IRB2022-00055), the Northwestern University Institutional Review Board (Shirley Ryan AbilityLab; IRB No. STU00216604), the BRANY Institutional Review Board (One Oncology Tennessee; IRB No. 24-08-131-652), and the University of Minnesota Institutional Review Board (IRB No. STUDY00021973). The study was conducted in accordance with the principles of the Declaration of Helsinki and all applicable human research regulations. Written informed consent was obtained from all participants prior to their participation in the study.

In-Clinic and Home-Based Monitoring Protocol

Clinical assessments were conducted as part of routine post–breast cancer care at each participating site. At enrollment, participants underwent standard clinical evaluations to characterize their baseline fluid status, including determination of the ISL stage of lymphedema. In-clinic BIA measurements were performed. All clinical data collected during these visits reflected information routinely obtained during standard patient care and were not collected solely for research purposes. Participants enrolled in the study received standardized instruction on the use of the home-based BIA device, and the initial home-based BIA measurement was performed in the clinic at the time of training. After returning home, participants were instructed to perform self-administered BIA measurements twice daily: once in the morning within 1 hour after waking as part of a consistent daily routine and once in the evening within 1 hour before bedtime to capture diurnal variations within a consistent daily routine. Adherence to this long-term self-monitoring schedule was encouraged to reflect real-world engagement without clinical supervision (see Figure 1).

Consistent with routine LE surveillance practices, participants attended in-clinic follow-up visits every 3 months over a 12-month period (at months 3, 6, 9, and 12). During these visits, lymphedema status was reassessed, and participants received guidance on self-management based on clinical findings, while continuing home-based BIA measurements throughout the monitoring period. Participants were referred for further treatment as clinically indicated based on in-clinic evaluation findings, including range-of-motion deficits, lymphedema symptoms, tissue or integumentary issues, and reduced function or mobility.

Conventional Criteria for BCRL

Conventional criteria were used to define the onset and stage of BCRL across participating institutions. In routine clinical practice, BCRL onset in the at-risk arm was assessed using circumferential tape measurements and volume-based criteria comparing the ipsilateral and contralateral upper extremities. Although site-specific clinical assessments were conducted according to local practice at each institution, lymphedema staging in this study was standardized using the widely accepted ISL classification system, including subclinical lymphedema (stage 0) and stages 1 - 3. Stage 0 was defined as a latent or subclinical condition characterized by impaired lymphatic transport without clinically apparent swelling, whereas stages 1 through 3 were defined according to ISL criteria based on the presence and progression of clinically observable edema and tissue changes. In this study, particular emphasis was placed on monitoring participants at stages 0 and 1, as these stages represent the subtle physiological fluid fluctuations that home-based BIA is designed to track over time. Throughout the study period in the clinical setting, all participants were managed while remaining asymptomatic or classified as stage 0 or 1, and no cases of stage 2 or 3 lymphedema were observed.

BIA Measurements

BIA measurements were obtained using an in-clinic device (InBody 770 [IB770]; InBody Co, Ltd) and a home-based device (BWA ON; InBody Co, Ltd). IB770 is a body composition analyzer widely used in body composition research and provides standard BIA-derived parameters, including fat-free mass, soft lean mass, body fat mass, and ECW/TBW ratios, with the ability to measure segmental ECW/TBW values. IB770 measurements were used as an in-clinic reference to evaluate the consistency of this metric across devices. Both systems are multifrequency bioimpedance analyzers designed to support region-specific assessment relevant to lymphedema surveillance. IB770 was used for standardized in-clinic assessments as part of routine clinical care, whereas BWA ON was used for self-administered home measurements, with results displayed via a dedicated mobile app on the participant's personal smartphone. Measurement data generated by BWA ON were assigned a unique participant-specific identifier and encrypted prior to transmission. Encrypted data were securely transferred through a cloud-based system to the participant's affiliated institution, where access was restricted to authorized health care professionals and researchers for clinical monitoring and research purposes. No directly identifiable personal information was stored or displayed within the app beyond what was required for secure data linkage.

Evaluation Criteria

Evaluation criteria were defined a priori to distinguish device-level agreement from longitudinal home-based measurement characteristics. The primary outcome was the agreement between the home-based BIA device (BWA ON) and the in-clinic reference device (IB770) to assess whether the home-based system provided measurements suitable for clinical monitoring. This comparison was based on paired measurements obtained during the initial in-clinic visit, at which both devices were used under standardized conditions. The secondary outcome focused on within-day variation in home-based BIA measurements obtained using BWA ON during daily self-monitoring. Specifically, differences in segmental ECW/TBW ratios between morning (before-noon) and afternoon (after-noon) measurements were evaluated to identify inherent diurnal variations that could influence the interpretation of long-term trends. In addition, analyses incorporated limb dominance as a clinically relevant factor, reflecting conventional bioimpedance interpretation practices in patients with lymphedema, in which dominant and nondominant limbs may

exhibit systematic physiological differences. Accordingly, secondary analyses examined whether diurnal changes in segmental ECW/TBW differed depending on whether the affected (at-risk) limb corresponded to the dominant or nondominant upper extremity. The feasibility of the monitoring system was evaluated based on participant adherence to the twice-daily measurement protocol.

Data Analysis

The analytic dataset consisted of repeated measurements of clinical lymphedema status (ISL stage), in-clinic BIA data (IB770), and longitudinal home-based BIA data (BWA ON). To evaluate agreement between the in-clinic and home-based BIA devices, the Lin concordance correlation coefficient (CCC) was used as the primary measure of agreement, supplemented by Pearson correlation coefficients and intraclass correlation coefficients (ICCs; two-way mixed-effects model with absolute agreement). Bland-Altman analysis was additionally performed to assess mean differences and 95% limits of agreement.

To illustrate the heterogeneity of home-based BIA change patterns within the ISL stage framework, grouped bar charts were used to visualize coexisting directional changes across stage transition categories. For diurnal variation analyses, paired *t* tests were conducted for only days where both morning (before-noon) and afternoon (after-noon) measurements were available to compare mean ECW/TBW differences at the individual level.

To account for the hierarchical and repeated-measures structure of the full longitudinal dataset, linear mixed-effects models (LMMs) were applied. In these models, measurement timing (before-noon vs after-noon) and limb status (affected vs unaffected) were treated as fixed effects, while participant IDs were included as random effects to control for within-individual correlation. Data distributions were examined and visualized using box plots and grouped bar charts to facilitate comparison across measurement conditions. Statistical significance was defined as a two-tailed *P* value of <.05. All statistical analyses were conducted using Python (version 3.13).

Results

Participant Demographics

A total of 37 female patients were initially enrolled in the study. However, two individuals who self-identified as ambidextrous were excluded from the analysis, as limb dominance was one of the key analytical variables in this study. For outcome analyses, participants were categorized based on ISL staging; however, stage 0 was further stratified to reflect longitudinal clinical status during the monitoring period. Specifically, participants who remained consistently within stage 0 throughout follow-up were distinguished from those who met the criteria for stage 0 but experienced transient fluctuations in clinical status during the study period. This stratification was applied to account for the known heterogeneity of subclinical lymphedema and to better capture differences in daily ECW distribution patterns observed through home-based bioimpedance monitoring.

At the time of program enrollment, all cases were unilateral with respect to the affected arm (right or left). In participants who had previously undergone bilateral mastectomy, those with a clearly defined affected and unaffected arm based on clinical management were included and monitored accordingly. For the final analysis, participants were categorized according to whether the affected arm was the dominant or nondominant limb, as limb dominance was a key variable of interest in this study. Baseline participant characteristics were therefore summarized by affected-side dominance (dominant vs nondominant). No statistically significant differences were observed across the four resulting groups with respect to age, body weight, or BMI.

Table . Participants' arm dominance and lymphedema status are shown along with demographic information (n=35).

Column headers	Dominant affected: stage 1	Dominant affected: stage 0	Nondominant affected: stage 1	Nondominant affected: stage 0
Participants, n	4	11	7	13
Age (years), mean (SD), range	49.75 (10.50), 41 - 62	51.45 (14.43), 34 - 82	57.29 (8.48), 45 - 68	51.69 (9.13), 39 - 66
Weight (kg), mean (SD), range	77.70 (21.26), 51.03 - 102.78	74.51 (19.07), 41.91 - 104.50	77.52 (7.65), 69.35 - 92.40	69.91 (10.07), 50.53 - 86.20
BMI (kg/m^2), mean (SD), range	28.93 (7.91), 18.72 - 37.71	27.52 (6.74), 17.81 - 38.43	28.89 (2.51), 24.00 - 31.81	26.13 (3.94), 20.38 - 33.46
Lesion side (R:L)[a]	4:0	10:1	0:6[b]	2:11
Surgery type (BM:UM:LP)[c]	0:1:1	2:1:1	3:0:4	1:7:5
Lymph-node procedure (ALND:SLND:SLNB)[d]	1:0:3	1:4:6	2:0:5	2:3:8

[a]R: right; L: left.

[b]One participant has no record of her lesion side.

[c]BM: bilateral mastectomy; UM: unilateral mastectomy; LP: lumpectomy.

[d]ALND: axillary lymph node dissection; SLND: sentinel lymph node dissection; SLNB: sentinel lymph node biopsy.

Patient-Led Home-Based Measurement Adherence

Adherence to the patient-led home-based BIA protocol is summarized in Table 2. Over the 12-month monitoring period, 35 participants across four geographically diverse sites (Honolulu, Hawai'i; Chicago, Illinois; Nashville, Tennessee; and Minneapolis, Minnesota) proactively contributed a total of 16,425 measurements using the BWA ON device. This high volume of data yielded an overall adherence rate of 64.3% relative to the recommended twice-daily measurement schedule.

Table . Patient engagement and adherence to the home-based bioelectrical impedance analysis measurement protocol over 12 months. The table summarizes the number of enrolled participants per site, the total volume of patient-led BWA ON measurements, overall adherence relative to the recommended twice-daily schedule, and the diurnal distribution (before vs after noon) of the recorded data.

Institution (site)	Number of participants, n	Total BWA ON tests, n	Adherence (%)	Before-noon tests, n (%)	After-noon tests, n (%)
1 (Honolulu, Hawai'i)	9	4325	65.8	2522 (58)	1803 (42)
2 (Chicago, Illinois)	6	2142	48.9	1225 (57)	917 (43)
3 (Nashville, Tennessee)	9	3662	55.7	1949 (53)	1713 (47)
4 (Minneapolis, Minnesota)	11	6296	78.4	3502 (56)	2794 (44)
Total	35	16,425	64.3	9198 (56)	7227 (44)

Notably, while adherence varied across sites—ranging from 48.9% (Chicago, Illinois) to 78.4% (Minneapolis, Minnesota)—all sites generated sufficiently dense longitudinal data to support the feasibility of extended, patient-driven monitoring in a real-world setting. Furthermore, as described in Table 2, the diurnal distribution of measurements was remarkably consistent across all regions. Before-noon measurements accounted for 56% of the total dataset, while after-noon measurements comprised 44%. This balanced distribution indicates that participants maintained a stable measurement routine regardless of their clinical site, ensuring sustained engagement with both daily measurement windows throughout the monitoring period. This consistency confirms that the home-based system is practical for capturing both morning and afternoon fluid status without clinical supervision.

Agreement Between in-Clinic and Home-Based BIA

To evaluate the agreement between the in-clinic BIA system (IB770) and the home-based device (BWA ON), paired measurements obtained at the enrollment visit were analyzed. Correlation analyses demonstrated strong positive associations between the two devices across all parameters, with correlation coefficients exceeding 0.99 for weight and percent body fat, and 0.86 for segmental ECW/TBW ratios. Of the 35 participants, two were excluded from the agreement analysis due to significant data entry errors in height (unit confusion between feet and inches), which resulted in physiologically implausible outliers. Therefore, the final agreement analysis was conducted with 33 participants.

Bland-Altman analyses showed minimal mean bias (0.001) for ECW/TBW measurements in both the affected and unaffected arms, with narrow 95% limits of agreement (Figure 2). ICC and CCC values further supported substantial agreement between the systems. Collectively, these findings indicate that home-based BIA measurements obtained using the BWA ON device are highly consistent with professional in-clinic standards. This high level of technical agreement supports the use of the home-based system as a reliable tool for high-frequency longitudinal monitoring, providing data quality comparable to standardized clinical assessments.

Figure 2. Bland-altman plots illustrating the agreement between home-based (BWA ON) and in-clinical (InBody 770) bioelectrical impedance analysis measurements. Panels represent (A) height, (B) weight, (C) BMI, (D) percent body fat (PBF), (E) ECW/TBW ratio of the affected arm, and (F) ECW/TBW ratio of the unaffected arm. The solid line indicates the mean bias, and the dashed lines represent the 95% limits of agreement (±1.96 SD). ECW: extracellular water; TBW: total body water.

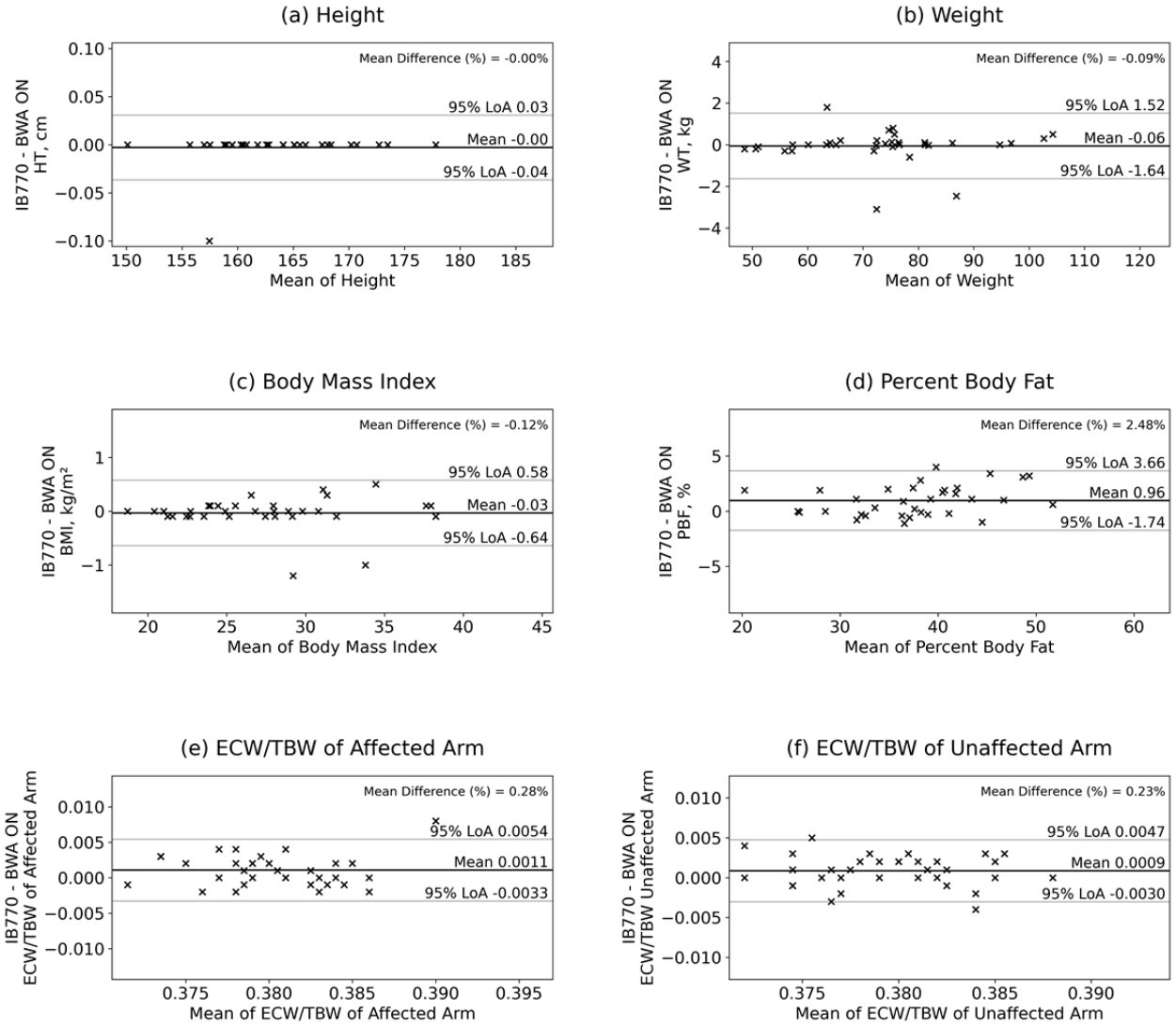


Table . Agreement between home-based (BWA ON) and in-clinic (InBody 770) bioelectrical impedance analysis measurement at enrollment (n=33). Agreement was evaluated using Bland–Altman analysis, intraclass correlation coefficients (ICCs, two-way mixed-effects model, and absolute agreement), and the Lin concordance correlation coefficient (CCC). Results are presented for anthropometric and body composition parameters, including weight, BMI, percent body fat (PBF), and segmental extracellular water–to–segmental total body water (ECW/TBW) ratios for the affected and unaffected upper extremities. Reported metrics include mean bias, SD of the error, 95% limits of agreement (LoA), proportion of measurements outside the LoA, ICC, *P* values, and CCC. Two participants were excluded from this analysis due to erroneous height input during the initial home-based measurement, resulting in extreme outliers.

Output	Mean error (bias)	SD of error (SD)	LoA lower limits	LoA upper limits	Proportion outside LoA (%)	ICC (3,1)	*P* value	CCC
Height	0	0.02	0	0	2.94	1	<.001	0.901
Weight	–0.1	0.8	–1.6	1.5	8.82	0.998	<.001	0.998
BMI	0	0.31	–0.6	0.6	5.88	0.998	<.001	0.974
PBF	1	1.38	–1.7	3.7	2.94	0.981	<.001	0.948
ECW/TBW affected arm	0.001	0.0022	–0.003	0.005	2.94	0.868	<.001	0.849
ECW/TBW unaffected arm	0.001	0.002	–0.003	0.005	5.88	0.889	<.001	0.886

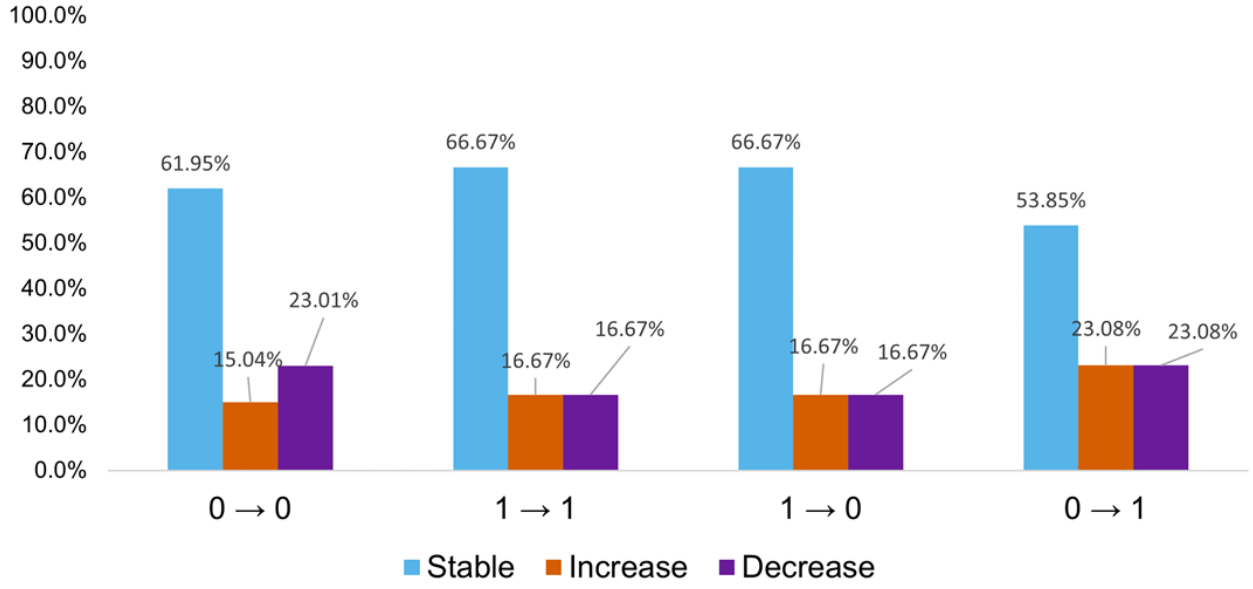
Longitudinal Changes in ISL Stage and Bioimpedance Parameters Over 12 Months

To evaluate longitudinal trends in ECW distribution over the 12-month monitoring period, participants' clinical lymphedema status was defined using ISL stage assessments obtained during five scheduled in-clinic visits for lymphedema management. These visits, occurring at approximately 3-month intervals, served as the reference standard for evaluating changes in edema status over time. Based on ISL staging across consecutive visits, temporal changes were categorized into four clinical transition patterns: worsening (stages 0-1), improvement (stages 1-0), stable low-risk status (persistent stage 0), and stable persistent status (persistent stage 1). These categories were designed to capture the full spectrum of LE progression and regression, as well as periods of clinical stability.

Corresponding to each clinical visit interval, home-based bioimpedance data were analyzed to determine whether segmental ECW trends measured by the BWA ON system exhibited concordant directional changes. The ECW/TBW ratio was used as the primary bioimpedance-derived indicator, with values exceeding 0.390 considered indicative of abnormal extracellular fluid accumulation. For each intervisit interval, changes in the ECW/TBW ratio were classified according to directional trends relative to the previous interval: a "decrease" reflected a shift toward edema improvement, an "increase" indicated a shift toward worsening, and minimal change was defined as "stable" status maintenance.

These bioimpedance-based transition patterns were examined in relation to the corresponding ISL stage transitions to assess whether home-based ECW/TBW trends reflected clinically observed changes. As illustrated in Figure 3, the results demonstrated that ISL stage classification alone does not fully capture the underlying heterogeneity of BWA ON change patterns. Across all stage transition categories, BWA ON measurements did not follow a uniform directional pattern. Notably, heterogeneous distributions were observed even within clinically stable groups (0→0 and 1→1), revealing substantial variability in bioimpedance behavior that remained undetected within the same clinical stage framework. These distinct distributions across clinical risk contexts suggest that patient-led monitoring provides a more granular level of physiological information than intermittent clinical staging.

Figure 3. Divergent ECW/TBW trends within the ISL stage framework. A 12-month longitudinal analysis. Grouped bar charts illustrate the inherent heterogeneity of home-based BIA directional patterns across clinical stage transitions. Notably, substantial variability in ECW/TBW behavior was observed even within clinically stable categories (0→0 and 1→1), indicating that segmental bioimpedance captures subtle physiological fluctuations not reflected by conventional ISL staging. These distinct distributions across clinical risk contexts highlight the increased granularity of high-frequency, patient-led monitoring compared to intermittent clinical assessments. BIA: bioelectrical impedance analysis; ECW: extracellular water; ISL: International Society of Lymphology; TBW: total body water.



Impact of Measurement Timing, Limb Dominance, and BCRL Status on Diurnal ECW/TBW Patterns

This analysis investigated whether ECW/TBW ratios obtained in a home-based environment demonstrated systematic variation according to measurement time within a day. Furthermore, we assessed how these ratios were influenced by the interaction between measurement timing, limb dominance (dominant vs nondominant), and BCRL status (stage 0 vs stage 1). These associations were evaluated using LMMs to account for the hierarchical nature of repeated measurements within participants.

Initially, we examined whether the ECW/TBW ratio of the affected arm varied according to measurement time (before-noon vs after-noon) and whether it differed depending on whether the affected arm corresponded to the dominant or nondominant limb. The results of the stepwise LMM are presented in Table 4. The estimated mean ECW/TBW ratio of the affected arm at the before-noon time point was 0.380 (intercept coefficient, $P<.001$). Compared to before-noon measurements, the after-noon ECW/TBW ratio was significantly decreased by 0.001 ($P<.001$). The between-group variance was minimal (group variance=0.000; $P<.001$), indicating that variability in the ECW/TBW ratio was primarily associated with measurement timing rather than interindividual differences.

Table . Linear mixed-effects model evaluating diurnal variation in the extracellular water (ECW)/total body water (TBW) ratios in the affected arm. The table presents the fixed effects of measurement timing (before-noon vs after-noon) on the segmental ECW/TBW ratio of the affected limb. The model demonstrates that systematic diurnal fluctuations significantly contribute to the variability of bioimpedance metrics, independent of interindividual differences. Statistical significance was defined as $P<.05$.

Fixed effect	Estimate	95% CI	*P* value
Fixed effects			
Intercept (before-noon)[a]	0.380	0.378 to 0.381	<.001
Diurnal change (after-noon)[b]	–0.001	–0.001 to –0.001	<.001
Random effect			
Participant (group variance)[c]	0.000	—[d]	<.001

[a]Intercept represents the baseline mean ECW/TBW ratio of all affected limbs measured during the before-noon period.

[b]Diurnal change indicates the estimated mean reduction in the ECW/TBW ratio during the after-noon period compared to the before-noon reference.

[c]Group variance represents the between-individual variance; a near-zero value indicates that variability is primarily driven by within-individual factors (measurement timing).

[d]Not applicable.

Based on the premise that limb dominance influences bioimpedance interpretation, we further stratified participants into four groups. The reference group consisted of participants whose dominant arm was affected and who consistently maintained stage 0 throughout follow-up (Same & non-BCRL). In this baseline group, the mean ECW/TBW ratio was estimated at 0.378 (P<.001), with a modest but significant afternoon decrease of 0.001 (P<.001). The results of this comprehensive interaction analysis are summarized in Table 5.

Table . Linear mixed-effects model of diurnal extracellular water (ECW)/total body water (TBW) ratio variations by limb dominance and breast cancer–related lymphedema (BCRL) status. The table illustrates the estimated differences in affected-arm ECW/TBW ratios between before-noon and after-noon measurements, stratified by limb dominance ("same" vs "different") and clinical BCRL status ("BCRL" vs "non-BCRL"). The "same & non-BCRL" group at the before-noon time point serves as the fixed reference. Statistical significance was defined as P<.05.

Fixed effect	Estimate	95% CI	*P* value
Intercept (Same and non-BCRL and before-noon)[a]	0.378	0.376 to 0.380	<.001
Same and BCRL and before-noon	0.002	–0.002 to 0.06	.28
Different and non-BCRL and before-noon	0.003	0.000 to 0.006	.047
Different and BCRL and before-noon	0.003	–0.000 to 0.007	.07
Same and non-BCRL and after-noon	–0.001	–0.001 to –0.001	<.001
Same and BCRL and after-noon	–0.002	–0.002 to –0.001	<.001
Different and non-BCRL and after-noon	0.000	0.000 to 0.001	<.001
Different and BCRL and after-noon	–0.000	–0.000 to 0.000	.32
Random effect (group variance)	0.000	—[b]	<.001

[a]Intercept: reference group representing participants with the dominant arm affected and consistent stage 0 status, measured during the before-noon period.

[b]Not applicable.

At the before-noon time point, the "different and non-BCRL" group showed a significant increase of approximately 0.003 compared with baseline (P=.047). The analysis of the interaction between time of day and group status revealed distinct diurnal patterns. Notably, the "same and BCRL" group exhibited a significantly greater reduction in the affected arm ECW/TBW ratio in the afternoon (interaction coefficient=−0.002; P<.001) than the baseline group. In contrast, the "different and non-BCRL" group reflected a significantly smaller afternoon decrease (interaction coefficient=−0.000; P<.001).

Overall, while absolute differences in mean ECW/TBW ratios across groups were relatively small, diurnal variation patterns differed significantly. The same and BCRL group exhibited the largest magnitude of afternoon decrease, suggesting that diurnal changes are closely associated with clinical BCRL status and daily loading of the dominant limb. The minimal random intercept variance indicates that variability was more strongly explained by within-individual factors—such as measurement timing—than by between-individual differences. This underscores the need for standardizing home-based measurements to a fixed morning time to ensure data interpretability and minimize inherent physiological noise in longitudinal self-monitoring strategies.

Discussion

Principal Findings

This study evaluated the technical agreement between in-clinic and home-based bioimpedance systems and characterized the longitudinal and diurnal patterns of segmental ECW/TBW ratios over 12 months. Our findings demonstrated that home-based BIA measurements using the BWA ON device are highly consistent with professional in-clinic standards (IB770), supporting the reliability of patient-led remote monitoring. However, longitudinal analysis revealed that ISL stage transitions do not always follow uniform BIA directional patterns, highlighting the inherent physiological heterogeneity within clinical stages. Notably, the linear mixed-effects model identified that measurement timing (diurnal variation) is a more significant driver of ECW/TBW variability than interindividual differences.

Technical Agreement and Feasibility of Patient-Led Monitoring

The strong agreement observed across all body composition parameters (Table 3), particularly the high ICC and CCC values for segmental ECW/TBW ratios, underscores the technical validity of home-based BIA. Despite the lack of clinical supervision, participants demonstrated sustained engagement, contributing over 16,000 measurements with a 64.3% adherence rate. This high volume of real-world data suggests that patient-led monitoring is not only feasible but also provides a

much denser data stream than intermittent clinic visits, which are typically limited to 3-month intervals.

Interpretation of Diurnal Variations and Limb Dominance

A key contribution of this study is the characterization of diurnal ECW/TBW fluctuations. While absolute differences between groups were small, the same and BCRL group (dominant arm affected with a history of BCRL) exhibited the most pronounced afternoon decrease (Table 5). This suggests that the dominant limb, which typically undergoes higher daily mechanical loading, may experience more dynamic fluid shifts in individuals with a history of lymphatic impairment. The near-zero group variance observed in our mixed-effects model further confirms that these fluctuations are primarily a function of measurement timing rather than inherent differences between individuals. Consequently, interpreting a single ECW/TBW value without considering the time of day may lead to clinical misinterpretation of a patient's edema status.

Clinical Implications for Remote Monitoring Protocols

Our results provide a practical evidence-based framework for standardizing home-based surveillance. Given that sustained twice-daily measurements may be logistically challenging for long-term self-care, we propose that home-based monitoring be standardized to a fixed morning time–ideally within 1 hour of waking and prior to daily physical activities. This standardization minimizes physiological "noise" caused by diurnal loading and ensures that longitudinal trends reflect true changes in lymphatic health rather than transient daily fluctuations.

Limitations and Future Work

This study has several limitations, including a relatively small sample size, which may limit the generalizability of the diurnal patterns across broader populations. Additionally, the 3-month interval for clinical ISL staging restricted our ability to correlate high-frequency BIA data with immediate clinical changes. Future research should use more frequent clinical assessments or digital symptom tracking to further validate the sensitivity of home-based BIA trends in capturing subclinical fluctuations.

Conclusion

In conclusion, home-based segmental bioimpedance analysis provides a reliable and technically valid method for longitudinal lymphedema surveillance. The significant impact of diurnal variation and limb dominance on ECW/TBW ratios highlights the necessity of standardized measurement protocols in remote health settings. By establishing consistent morning measurement routines, patient-led monitoring can provide granular, high-quality data that complement traditional in-clinic care, supporting more precise and personalized management for breast cancer survivors at risk for lymphedema.

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Authors' Contributions

Conceptualization: CT, JF, and SS
Data curation: CT, LB, EM, and DH
Formal analysis: YH, and HK
Writing–original draft: MP
Writing–review & editing Interpretation: YH and LK

Conflicts of Interest

None declared.

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Abbreviations

ALND: axillary lymph node dissection
BCRL: breast cancer–related lymphedema
BIA: bioelectrical impedance analysis
CCC: concordance correlation coefficient
ECW: extracellular water
IB770: InBody 770
ICC: intraclass correlation coefficient
ISL: International Society of Lymphology
LMM: linear mixed-effects model
TBW: total body water

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Effect of a Spinal Orthosis With Leaf Spring and Programmable Local Vibration on Kyphosis Angle and Trunk Muscle Strength in Hyperkyphosis: Development and Feasibility Study

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Abstract

Background: The application of spinal orthoses and local vibration in the treatment of hyperkyphosis is a developing concept. Further research is needed to determine the impact of leaf springs and local vibration techniques on the neuromusculoskeletal system.

Objective: This study aimed to evaluate the effect of the simultaneous application of a leaf spring and a programmed local vibration system in a spinal orthosis on thoracic kyphosis angle (TKA) and the function of trunk flexor and extensor muscles.

Methods: We used a soft thoracolumbar orthosis as a base for 2 parallel leaf spring bars made from AISI (American Iron and Steel Institute) 1075 steel (45 cm × 2 cm × 2 mm each). We added 4 solenoid actuators (60 g each) housed in 2 units positioned 12 cm apart, generating 20 N vertical force at 8 Hz frequency with 10 mm free displacement. A programmable Arduino microcontroller delivered 10-second vibration bursts followed by 5-minute rest intervals, repeated for 12 cycles per session, applied every other day. One participant with hyperkyphosis (baseline TKA=47.24°) used this device for 4 weeks. Outcomes included TKA (measured by photogrammetry) and trunk muscle function (assessed under isometric, isotonic, and isokinetic conditions). Feasibility outcomes included adherence, wear time, and adverse events.

Results: Bench testing confirmed an 8 Hz vibration frequency, a 10 mm free displacement, and an on-body contact pressure of 9.5 N/cm² (95 kPa). In the short-term assessment (N=10), mean acceptability scores were 7.95 (SD 0.83) for appearance and 7.6 (SD 0.07) for comfort, and no skin-related adverse events occurred. In the 4-week single-participant pilot (N=1), adherence was 100% (12/12 sessions completed), mean daily wear time was 1.4 (SD 0.3) hours, and no adverse events were reported. TKA decreased from 47.24° to 45.81° (change: −1.43°), which did not exceed the minimal detectable change (4.62°). Pre-post changes in muscle function outcomes are reported descriptively.

Conclusions: A semirigid thoracolumbar orthosis with integrated programmable vibration (8 Hz, 20 N free force) is technically feasible, showing reliable bench performance. Short-term assessment in 10 participants indicated acceptable comfort and appearance with no immediate safety concerns. The 4-week single-participant pilot demonstrated 100% adherence and no adverse events. The observed 1.43° kyphosis reduction was not clinically meaningful (below minimal detectable change). Larger controlled studies are needed to determine whether this device improves muscle function or spinal alignment.

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KEYWORDS

spine; orthotic devices; muscle strength; kyphosis; vibration

Introduction

Spinal orthoses have undergone significant evolution over decades, progressing from rigid immobilization devices to sophisticated soft exoskeletons designed to enhance functionality and patient outcomes [1]. Early iterations primarily used rigid structures to apply corrective or limiting forces, proving effective for postsurgical stabilization, injury protection, and the management of spinal deformities such as scoliosis and kyphosis [2]. However, the long-term adverse effects of rigid immobilization—including muscle atrophy and decreased bone mineral density—highlighted the need for alternative approaches [3]. This led to the development, by the late 1990s, of the first biomechanically informed orthoses incorporating semirigid and soft structures for kyphosis management [4].

Today, semirigid thoracolumbar orthoses are a standard conservative intervention for reducing thoracic kyphosis and

improving muscle strength in postural and age-related hyperkyphosis [1]. While clinically effective, evidence suggests that they may not represent the most efficient conservative method for either kyphosis reduction or strengthening back musculature [5]. Consequently, orthotic design has continued to advance. A key development was the 2004 introduction of the Spinomed orthosis, which demonstrated improved outcomes [6]. Throughout this progression, the integration of leaf springs has been a notable feature, associated with significant clinical effectiveness [7,8]. Nonetheless, research has largely focused on therapeutic end points rather than on optimizing the material properties of the springs themselves [1].

Our previous work investigated leaf springs fabricated from AISI (American Iron and Steel Institute) 1075 carbon steel, a common and widely available material [8]. Although effective, the intervention produced a mean reduction in thoracic kyphosis of 8.14° (SD 10.5°), which was less than the 11.76° (10.4°) reduction achieved with the Spinomed orthosis [6]. Both orthotic interventions were, in turn, outperformed by supervised exercise training, as identified in a meta-analysis [5]. This performance gap underscores the need for further innovation in orthotic design.

To enhance the efficacy of semirigid thoracolumbar orthoses, we propose integrating a programmable local vibration system. Local vibration is a recognized intervention for mitigating muscle soreness and fatigue [9] and can promote muscle hypertrophy [10]. Although prior studies have explored vibration as a postural reminder in young populations with hyperkyphosis [11], its application for muscle strengthening in age-related hyperkyphosis—a condition strongly correlated with decreased back extensor strength [12]—remains underexplored. Commonly used displacement probes in muscular rehabilitation lack consistent evidential support [13], and concerns persist regarding potential muscle weakness from improper use. A programmable system could address these safety concerns, ensuring controlled application to protect muscle and skin integrity.

Spinal orthoses have evolved significantly from rigid, immobilizing braces toward semirigid and soft exoskeletons that aim to support function while mitigating the muscle atrophy and bone density loss associated with rigid designs [1,14,15]. While effective for stabilization, rigid structures often lead to discomfort and restricted mobility. Semirigid thoracolumbar orthoses now represent a standard conservative intervention for age-related hyperkyphosis, aiming to reduce the thoracic kyphosis angle (TKA) and improve back extensor strength [1]. Key innovations, such as the Spinomed orthosis and the integration of biomechanically tuned leaf springs, have enhanced corrective outcomes and trunk support [7,16]. However, despite these advancements, orthotic interventions generally remain less effective than supervised exercise programs, which meta-analyses have identified as producing superior kyphosis reduction through targeted strengthening [1,15-17].

Current orthotic research emphasizes clinical outcomes over material optimization [18], leaving potential for enhanced spring designs to close the efficacy gap with exercises [5]. Leaf spring materials for orthoses have been studied, with focus on optimizing flexibility, strength, and weight [7,8,16]. Common materials used in leaf springs include AISI 1075 carbon steel and composite polymers such as carbon fiber–reinforced plastics. Carbon fiber composites exhibit superior stiffness-to-weight ratios and fatigue resistance compared to traditional steel springs, leading to lighter orthoses with improved energy return and durability. Studies comparing steel and composite leaf springs report that composites exhibit up to ~30% higher stiffness and significantly lower stress under load, which may be beneficial for sustained corrective forces while reducing the risk of material fatigue. Thermoplastics with adjustable molding properties also allow customizable fit without compromising spring performance [19,20]. These material advances enable tunable mechanical properties in leaf springs for tailored spinal support devices [14].

Comparing the Spinomed orthosis versus exercise outcomes in hyperkyphosis, several randomized studies and meta-analyses find both interventions to be effective in reducing kyphosis angle and improving back extensor strength [21]. The Spinomed orthosis improves spinal alignment and muscle endurance by providing postural support and facilitating muscle activation, with kyphosis angle reductions reported between 7° and 12° after months of use [16,22]. However, recent randomized controlled trials of semirigid thoracolumbar orthoses in older adults with hyperkyphosis report improvements in TKA, trunk muscle strength, and balance after orthosis use for 6 to 12 weeks. One trial showed significant kyphosis reduction and increased isometric trunk extensor and flexor strength using a semirigid backpack-style orthosis compared to no treatment. Another randomized controlled trial demonstrated that Spinomed orthosis improved back muscle maximal voluntary contraction and balance parameters, highlighting muscle facilitation effects. However, trials underscore that orthoses often provide modest benefit relative to targeted exercise regimens, and none included programmable local vibration systems integrated with springs to date [8,16,23]. Meta-analyses highlight no significant difference between Spinomed orthosis and posture training support for immediate improvements, but supervised exercise tends to surpass orthoses in long-term outcomes [17]. Exercise programs, particularly those focusing on back extensor strengthening and postural training, often achieve greater kyphosis reductions and functional gains than orthoses alone, although adherence and safety vary [5,21].

Biomechanical analyses of leaf spring placement and force transmission in spinal supports emphasize critical design parameters, including spring position relative to spinal curvature, attachment points, and force vector alignment with anatomical axes. Optimal positioning on the posterior thoracolumbar region allows the application of assistive or resistive forces tailored to patient posture and muscle capacity. Modeling studies using finite element analysis and musculoskeletal simulations show that leaf springs modulate spinal loading by offloading vertebral structures and enhancing muscle activation through controlled resistance. Variations in spring material, thickness, and length affect stiffness and corrective moment magnitude, influencing comfort and clinical efficacy. These biomechanical insights guide the engineering of orthotic designs that dynamically interact with trunk biomechanics for improved kyphosis management [14,19,24]. Leaf springs function by selectively

assisting or resisting trunk movements to offload bony and soft tissues or augment muscular performance. Their configuration—including positioning, attachment, material type, thickness, and length—dictates the magnitude and direction of the applied force, making them versatile for both exoskeletal and orthotic applications [14]. In exoskeletons, leaf springs are primarily protective, engineered to reduce lumbar loading during lifting or minimize strain during repetitive tasks [25]. They are typically offset from the body to align centers of rotation, generating corrective momentum while mitigating mechanical stress on anatomy and skin irritation from rigid contact [26,27]. In spinal orthoses, however, leaf springs are used chiefly to induce corrective spinal positioning. Positioned parallel and posterior to the spine, they apply controlled resistive or assistive forces directly to the torso to improve muscle function and, consequently, spinal alignment [6,8]. Unlike in exoskeletons, they often maintain direct body contact, with spacing adjustments used to modulate force or permit limited postural adjustment without rigid immobilization.

Whole-body vibration training and localized vibration systems have been shown to increase muscle mass and strength, counteracting sarcopenia and muscle fatigue. Randomized trials demonstrate that vibration frequencies around 60 Hz, with controlled amplitude, significantly enhance lower limb muscle activation and strength gains in seniors. Local vibration therapy, while established for muscle hypertrophy and fatigue reduction in sarcopenic older adults [28], remains underexplored in spinal orthoses for hyperkyphosis-related back extensor weakness. Prior applications focused on postural cues in young participants rather than strength gains in older individuals with hyperkyphosis [11,29,30]. Investigations integrating local vibration with spinal orthoses have primarily used parameters (eg, frequency, force amplitude) designed to enhance proprioception and postural awareness, rather than to induce muscular strengthening. To date, the application of local vibration within spinal supports has been limited primarily to serving as a postural reminder or neuromuscular stimulator in young, healthy participants [11,30]. Prior to the data derived from this study [31], no research on spinal orthotics had explicitly investigated local vibration with the primary goal of improving muscle strength. Using vibration parameters intended for strength adaptation in a wearable device, without a programmed and controlled application, carries a risk of adverse effects, including potential damage to skin and muscle tissues. This highlights the novelty of programmable vibration integration for safe, controlled muscle stimulation.

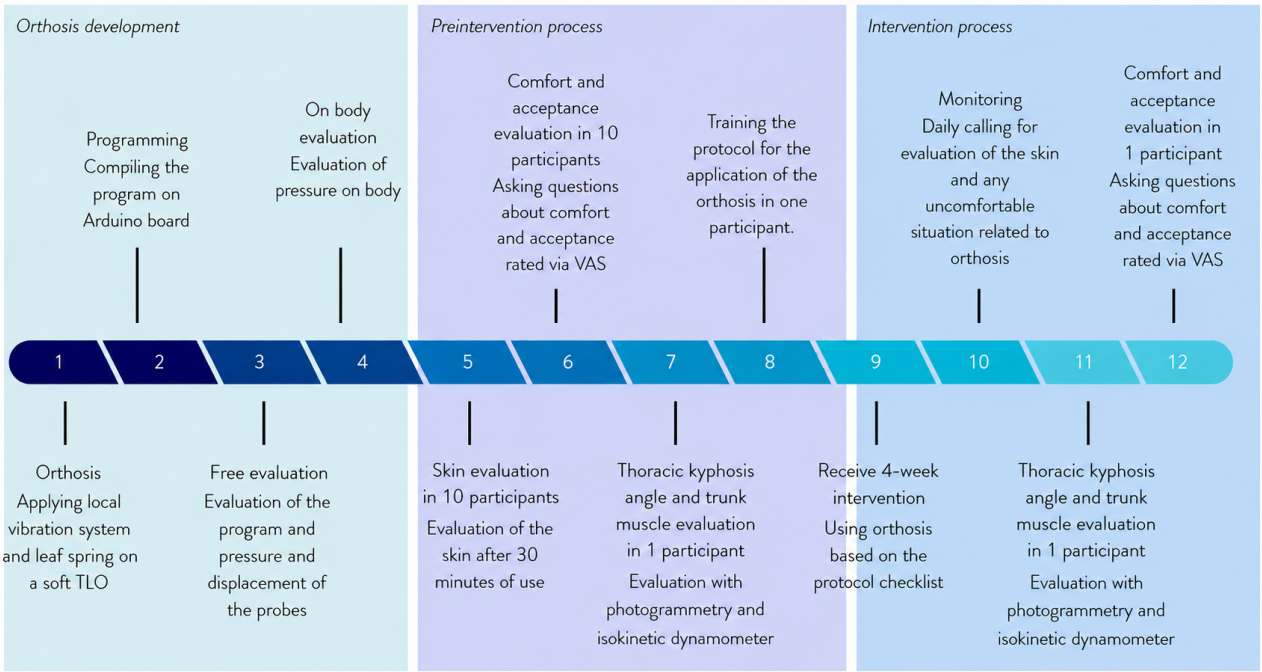
Programmable vibration devices allow safe, adjustable stimulation intensity addressing concerns about muscle or skin injury, making them a promising adjunct in geriatric orthopedic rehabilitation [31]. This study details the technical development and feasibility evaluation of a novel orthosis, based on the results from the first author's doctoral research. It also specifically focuses on the technical specifications and development process of a novel semirigid thoracolumbar spinal orthosis equipped with 2 leaf springs and a programmable local vibration system, designed to reduce TKA and improve trunk muscle strength.

Methods

Study Design

This study comprised 3 sequential phases: (1) technical development and bench testing of the orthosis, (2) short-term (30 min) comfort, acceptability, and safety assessment in 10 participants with hyperkyphosis, and (3) a 4-week single-participant pilot to explore pre-post changes in TKA and trunk muscle function. The study was conducted in the orthotics and prosthetics department and the cumulative laboratory of the University of Social Welfare and Rehabilitation Sciences. To better understand the events, the implementation steps of the study are shown in Figure 1.

Figure 1. Implementation steps of the study including events in each section. TLO: thoracolumbar orthosis; VAS: visual analog scale.



Participants

Short-Term Assessment (Phase 2)

Ten participants with hyperkyphosis were enrolled to evaluate orthosis acceptability, comfort, and skin safety following a 30-minute wear trial. Participants were recruited from university faculties via email announcements.

Four-Week Single-Participant Pilot (Phase 3)

Following the short-term assessment, 1 participant proceeded to a 4-week usability trial.

Inclusion Criteria

The inclusion criteria for both phases are as follows: age 40 to 60 years, TKA>45° measured by photogrammetry, BMI of 25 to 33 kg/m², and the ability to walk independently without assistive devices while wearing the orthosis.

Exclusion Criteria

The exclusion criteria for both phases are as follows: osteoporosis (T-score <−2.5), recent osteoporotic vertebral fracture (within the past 6 mo), hyperkyphosis due to congenital or structural causes (eg, hemivertebra, Scheuermann disease), scoliosis (Cobb angle >10°), spinal canal stenosis, spinal tumors or infections, use of medications known to cause muscle weakness, diabetes with peripheral neuropathy or myopathy, and any spinal degenerative disease or neuropathic pain affecting the back or lower limbs [31].

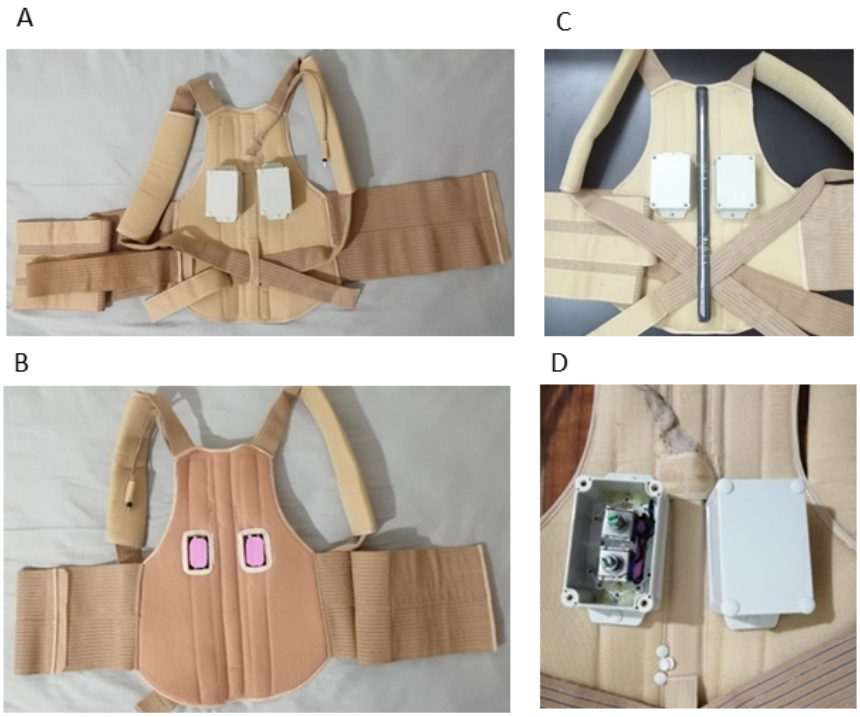
Phase 1: Technical Development and Bench Testing

Orthosis Development

The orthosis consisted of a soft thoracolumbar support structure incorporating 2 parallel leaf springs fabricated from AISI 1075 steel (each 45 cm length × 2 cm width × 2 mm thickness). The support structure included 2 shoulder straps, each 70 cm in length, constructed from a dual-layer elastic fabric. The straps originated at the level of the seventh cervical vertebra (C7) and extended anteriorly and inferiorly over the shoulders, crossing each other posteriorly at approximately the level of the first lumbar vertebra (L1). They were then secured anteriorly over the abdomen via stitching to the lumbar elastic bands. The lumbar bands provided spinal coverage through a 2-step fastening system comprising wide elastic straps (Figure 2).

The leaf spring was custom-contoured to match the user's thoracic and lumbar spinal curvature. In accordance with semirigid orthosis alignment protocols, the proximal portion was formed with a 4-cm offset from the spinal column. This spacing permitted an adequate range of motion for trunk movements while facilitating TKA reduction.

Figure 2. (A) and (B) The support structure. (C) The leaf spring position. (D) The placement of vibration units in the orthosis.



Local Vibration System

The vibration system included 4 solenoid actuators (60 g each) housed in 2 units (20 g each), positioned 12 cm apart vertically. Each solenoid generated 20 N vertical force at 8 Hz frequency with 10 mm free displacement. A programmable Arduino microcontroller delivered 10-second vibration bursts followed by 5-minute rest intervals, repeated for 12 cycles per session. Vibration was applied every other day (ie, 3 - 4 sessions per week). The total electromechanical system mass was 300 g.

The vibration probes were strategically positioned over the paraspinal musculature between the T6 and T12 vertebral levels to target the erector spinae muscle group while avoiding direct vertebral column contact.

Battery and Thermal Protection System

The battery pack integrated a thermal fuse (72 °C, SD 3 °C), a battery management system (3 S, 10 A), and a polyfuse (10 A hold, 20 A trip) for safety. All electronic components (batteries, Arduino microcontroller, relays, and power switches) were housed in a separate portable control box, connected to the orthosis only during active vibration sessions. The solenoids were the only electronic elements permanently attached to the orthosis structure.

Bench Testing Measurements

Free Displacement and Vibration Frequency

The free displacement (amplitude) of the probes and the baseline vibration frequency (under no external load) were measured using high-speed video recording. Video playback was analyzed in slow motion to quantify oscillations per second (Hz).

Pressure

The pressure exerted by the vibration probes was measured under 2 conditions: (1) *free vibration*, with the system secured in a stabilizing box to maintain solenoid perpendicularity, and (2) *on-body vibration*, with the sensor placed between the orthosis-mounted probe and a healthy volunteer's back. A 16×16 cm force-sensing resistor array integrated with the Pliance system (Novel GmbH) recorded pressure magnitude and distribution.

Weight

The total weight of the orthosis was measured, both with and without the integrated vibration system.

Phase 2: Short-Term Comfort, Acceptability, and Safety Assessment (N=10)

Ten middle-aged participants with hyperkyphosis evaluated the orthosis appearance and comfort using 10-point numerical rating scales (0=completely unpleasant; 10=completely pleasant) for 2 items: (1) "Rate the orthosis's appearance" and (2) "Rate the orthosis's user-friendliness." Each participant wore their size-matched orthosis for 30 minutes before providing feedback.

Skin safety was assessed via visual inspection [32] performed by a certified orthotist specializing in spinal orthoses. The evaluation was based on the presence of redness or abnormal skin color changes following a standardized fitting protocol. This protocol included an initial skin evaluation prior to orthosis application and a second evaluation after 30 minutes of wear [33]. Any observed erythema was expected to resolve within 20 minutes of orthosis removal. Persistent skin discoloration beyond this 20-minute period was recorded as an adverse event.

Phase 3: Four-Week Single-Participant Pilot (N=1)

Following the short-term assessment, a single-participant pilot study was conducted. The participant (45-year-old woman, baseline TKA=47.24°) underwent a baseline assessment, orthosis fitting, and a 30-minute orientation session.

Intervention Protocol

Week 1 involved gradual adaptation, increasing wear time from 10 minutes. Weeks 2 to 4 involved maintenance wear of 1 to 2 hours daily (self-scheduled). Vibration (12 cycles of 10-s bursts with 5-min rests) was applied every other day. Throughout the intervention, the examiner made brief phone calls to monitor comfort and any adverse effects. The participant maintained a daily wear-time log.

Outcome Measures (Phase 3)

Thoracic Kyphosis Angle

TKA was assessed using photogrammetry, which demonstrates high test-retest reliability (intraclass correlation coefficient=0.97°; standard error of measurement=1.67°; minimal detectable change [MDC]=4.62°) [34,35]. The participant positioned herself on a marker while a calibrated camera (Canon 8 Mpixel MV150i; Canon Inc) captured 3 digital images of markers located on the seventh cervical and twelfth thoracic spinous processes [36]. Images were analyzed using AutoCAD (Autodesk, Inc) to compute angles, with the average of the 3 angles documented as TKA.

Trunk Flexor and Extensor Muscle Tests

Muscle function was assessed using a HUMAC-NORM isokinetic dynamometer (v.12.001.0005; CSMi) in the standing (orthostatic) position. System reliability in standing was 0.98 (Reyes-Ferrada et al, 2022). Table 1 summarizes the isometric, isotonic, and isokinetic test protocols.

Table . Summary of isometric, isotonic, and isokinetic test protocols.

Parameter	Isometric	Isotonic (eccentric or concentric)	Isokinetic concentric
Test mode	Isometric	Isotonic (constant load)	Isokinetic concentric
Test angle or ROM[a]	15° flexion	5° extension to 30° flexion	5° extension to 30° flexion
Speed	N/A[b]	Participant-controlled	60°/s
Evaluation torque	N/A	10 Nm	N/A
Warmup	Submaximal contractions (3 trials)	3 cycles familiarization	3 submaximal cycles
Trials	3 maximal per muscle group	3 cycles per mode	5 maximal repetitions
Rest intervals	30 seconds between trials; 1 minute between groups	30 seconds between trials	30 seconds between trials
Visual feedback	Off	Off	Off
Key variables	Peak torque, average torque, time to peak torque	Peak power, work per repetition, joint angle at peak power	Peak torque, work per repetition, time to peak torque

[a]ROM: range of motion.

[b]N/A: not applicable.

Feasibility Outcomes

Feasibility outcomes were assessed using descriptive statistics: adherence (percentage of prescribed sessions completed), wear time (minutes per day; mean, SD), device issues (frequency and type), and safety (number and severity of adverse events).

Pain and Usability Assessment

The participant rated ease of wearing, ease of use, weight, and appearance using 0 to 10 rating scales postintervention.

Statistical Analysis

Study Design and Data Structure

This feasibility study used a single-participant pre-post design. The same participant underwent outcome assessments before and after a 4-week intervention, yielding paired observations for each outcome measure.

Clinically Meaningful Change Thresholds

A priori decision rules were established to determine whether observed changes were clinically meaningful. Thresholds were derived from published MDC values and percentage change criteria from orthosis and vibration literature [16,31,34].

Feasibility Outcomes

Feasibility outcomes were assessed using descriptive statistics: adherence (percentage of prescribed sessions completed), wear time (minutes per day; mean, SD), device issues (frequency and type), and safety (number and severity of adverse events).

Ethical Considerations

This study was approved by the Ethics Committee of the University of Social Welfare and Rehabilitation Sciences (approval: IR.USWR.REC.1401.217) in January 2023.

Results

Phase 1: Technical Specifications and Bench Testing Performance

The electromechanical vibration module affixed to the orthosis had a total mass of 300 g, comprising 2 housing units (20 g each) and 4 solenoid actuators (60 g each).

Vibration Frequency

An 8 Hz vibration frequency was verified using video recording. Footage of the active module was analyzed using DaVinci Resolve Studio software (v.20.0.1.6; Blackmagic Design Pty Ltd). The analysis confirmed that the probe achieved its maximum displacement from the solenoid body 8 times per second, corresponding to the target 8 Hz frequency.

Mechanical Pressure

Pressure was quantified using a Pliance system (Novel GmbH). The peak force measured in the free-state was 251.2 N. Given the circular probe's cross-sectional area of 12.56 cm^2, this equated to a contact pressure of 20.0 N/cm^2 (200 kPa). During on-body use, the peak force decreased to 119.3 N, resulting in a measured contact pressure of 9.5 N/cm^2 (95 kPa).

Probe's Free Displacement

The maximum linear displacement of the solenoid probe was measured as 1.0 cm from its resting position.

Phase 2: Short-Term Comfort, Acceptability, and Safety Assessment (N=10)

Ten participants with hyperkyphosis evaluated the orthosis. Their mean age was 62.2 (SD 7.83) years, and their mean TKA was 55.53° (SD 1.69°). The average score for appearance was 7.95 (SD 0.83), and the average score for comfort was 7.6 (SD 0.07). Detailed demographic data and individual responses are reported in Table 2. No skin-related adverse events were observed following the 30-minute wear trial.

Table . Demographic data and feedback from phase 2 participants (N=10).

Participants	Age, y	Gender	Height, m	Weight, kg	TKA[a]	Appearance score	Comfort score
1	64	Woman	1.70	69.00	49.31°	9.5	8
2	60	Woman	1.63	60.00	56.89°	9	8
3	60	Woman	1.65	67.00	56.07°	8	8
4[b]	62	Woman	1.57	55.00	61.26°	8	7
5	62	Woman	1.52	58.00	57.41°	8	8
6	62	Woman	1.49	66.00	53.33°	8	6
7	63	Woman	1.55	69.00	50.41°	7	8
8	67	Woman	1.50	70.00	63.25°	8	8
9[c]	77	Man	1.76	90.00	60.11°	7	7
10	45	Woman	1.50	51.00	47.24°	7	8
Mean (SD)	62.2 (7.83)	—[d]	1.59 (0.09)	65.5 (10.82)	55.53° (1.69°)	7.95 (0.83)	7.6 (0.07)

[a]TKA: thoracic kyphosis angle.

[b]Mentioned unpleasant characteristics: heavy.

[c]Mentioned unpleasant characteristics: hard to wear.

[d]Not applicable.

Phase 3: Four-Week Single-Participant Pilot—Pre-Post Changes

Feasibility and Adherence Outcomes

A 45-year-old woman with hyperkyphosis used the orthosis with the local vibration system every other day for 4 weeks. Feasibility and adherence outcomes are summarized in Table 3.

Table . Feasibility and adherence outcomes.

Feasibility metric	Result	Target	Whether target met
Adherence			
Prescribed sessions (total)	12	12	Yes (100%)
Completed sessions	12	12	Yes (100%)
Missed sessions	0	0	Yes
Wear time (h)			
Prescribed daily wear	1 - 2	1 - 2	Yes
Actual mean (SD) daily wear	1.4 (0.3)	1 - 2	Yes
Total wear time over 4 weeks	39.2	28 - 56	Yes
Device issues			
Technical failures	0	0	Yes
Battery depletion during session	0	0	Yes
Skin adverse events	0	0	Yes
Reported discomfort (0 - 10 scale)	2/10	<4/10	Yes
Acceptability (postintervention; 0 - 10 scale)			
Ease of wearing	8	≥7	Yes
Ease of use	7	≥7	Yes
Weight acceptance	7	≥6	Yes
Appearance	5	≥5	Yes (borderline)

Thoracic Kyphosis Angle

TKA was 47.24° preintervention and 45.81° postintervention (change: −1.43°). This change did not exceed the MDC value of 4.62° reported for photogrammetry [34], indicating that the observed reduction was not clinically meaningful.

Trunk Muscle Function: Pre-Post Changes

Preintervention and postintervention values for all muscle function outcomes are described in Table 3. Isometric extensor peak torque increased from 19 to 24 Nm (+5 Nm). Isometric flexor peak torque decreased from 34 to 25 Nm (−9 Nm). Isokinetic concentric flexor peak torque increased from 6 to 20 Nm (+14 Nm). Isokinetic concentric extensor peak torque increased from 12 to 20 Nm (+8 Nm). Complete descriptive results for isometric, isotonic, and isokinetic tests are presented in Table 4.

Table . Decision rules for clinically meaningful change.

Outcome	Threshold type	Threshold value	Observed change	Whether threshold met	Decision
TKA[a] reduction	MDC[b]	≥4.62°	1.43°	No	Not clinically meaningful
Isometric extensor torque	% change	≥15%	+26.3%	Yes	Clinically meaningful
Isokinetic extensor torque	% change	≥20%	+66.7%	Yes	Clinically meaningful
Isokinetic flexor torque	% change	≥20%	+233%	Yes	Clinically meaningful
Time to peak torque	% reduction	≥15%	−55.2%	Yes	Clinically meaningful
Adherence to protocol	% completion	≥80%	100%	Yes	Feasible
Adverse events	Count	0	0	Yes	Safe

[a]TKA: thoracic kyphosis angle.

[b]MDC: minimal detectable change.

Pain and Usability Assessment

The participant assigned the orthosis scores of 8 out of 10 for ease of wearing, 7 out of 10 for ease of use, 7 out of 10 for weight, and 5 out of 10 for appearance. No adverse events were reported during the 4-week intervention.

Discussion

Overview

This technical note describes the development and feasibility evaluation of a semirigid thoracolumbar orthosis integrating a programmable local vibration system. The study had 3 phases: (1) bench testing confirming technical specifications (8 Hz, 10-mm free displacement, 9.5 N/cm² on-body contact pressure); (2) short-term assessment in 10 participants showing acceptable comfort (7.6 out of 10) and appearance (7.95 out of 10) with no skin safety concerns; and (3) a 4-week single-participant pilot demonstrating 100% adherence, no adverse events, and descriptive pre-post changes in kyphosis angle and muscle function outcomes.

Technical Feasibility

The bench testing confirmed that the electromechanical system met its design specifications. The 8-Hz vibration frequency was reliably achieved, and the on-body contact pressure of 9.5 N/cm² (95 kPa) was lower than the free-state pressure (20.0 N/cm²) due to tissue compliance and padding. This reduction is consistent with previous reports of wearable vibration devices [32] and suggests that the system delivers mechanical stimulation within a range that is likely safe for soft tissue, though formal tissue tolerance studies would be needed to confirm.

The choice of 8 Hz frequency warrants discussion. While higher frequencies (30 - 60 Hz) are often used for proprioceptive training [37,38], lower frequencies (8 - 15 Hz) have been shown to improve muscle strength with potentially lower risk of tissue irritation [39,40]. Since participants in this study received vibration during seated isometric postural holding, 8 Hz was selected as a conservative starting point that balances potential neuromuscular effects with safety. The 10-second vibration bursts with 5-minute rest intervals were based on neurophysiological evidence indicating that muscle spindle afferents require approximately 6 seconds to return to baseline activity following mechanical stimulation [41].

Short-Term Acceptability and Safety (Phase 2)

The short-term assessment in 10 participants with hyperkyphosis revealed acceptable scores for appearance (7.95/10) and comfort (7.6/10). Among these participants, 3 noted specific concerns: 1 reported the orthosis was “heavy,” 1 reported it was “hard to wear,” and 1 reported no specific concerns. No skin-related adverse events were observed after 30 minutes of wear. These findings suggest that the orthosis is acceptable for short-term use, though the “hard to wear” comment highlights the need for improved donning instructions or design modifications.

Four-Week Single-Participant Pilot (Phase 3)

Feasibility

The participant completed all prescribed sessions with a mean daily wear time of 1.4 (SD 0.3) hours, meeting the prescribed target of 1 to 2 hours. No technical failures, battery depletions,

or adverse events occurred. These feasibility metrics support the safe application of the device for home use in future larger studies.

Thoracic Kyphosis Angle

The observed reduction of 1.43° (from 47.24° to 45.81°) did not exceed the MDC=4.62° established for photogrammetry [34]. Therefore, this change cannot be interpreted as a clinically meaningful improvement. Possible explanations for the modest change include the short intervention duration (4 wk) or the mild baseline kyphosis (<52°). Future studies with longer intervention periods and participants with more severe kyphosis may be needed to detect meaningful spinal alignment changes.

Muscle Function Outcomes Based on Descriptive Findings

Pre-post changes in muscle function are reported descriptively (Table 3) and should be interpreted with caution, given the single-participant design. Several observations are noted, including the following: isometric extensor peak torque increased by 5 Nm (from 19 to 24 Nm), whereas isometric flexor peak torque decreased by 9 Nm (from 34 to 25 Nm). Isokinetic concentric peak torque increased for both flexors (from 6 to 20 Nm) and extensors (from 12 to 20 Nm). Time-to-peak torque decreased for both flexors and extensors across several test types.

While these descriptive changes are notable, they cannot be attributed to the intervention with certainty due to the absence of a control group, repeated measures, or inferential statistics. The patterns observed may reflect true neuromuscular changes, practice effects, measurement variability, or a combination of factors. Importantly, no electromyography or mechanistic measurements were collected; therefore, proposed mechanisms such as altered cocontraction, reciprocal inhibition, or motor unit recruitment remain speculative hypotheses requiring direct investigation in future studies.

Previous studies of local vibration in spinal orthoses have primarily used vibration as a postural reminder (eg, 30 - 60 Hz vibration motors) rather than as a therapeutic stimulus for muscle strengthening [11,29,30]. These studies reported reductions in kyphosis angle of approximately 8° after 4 days of use [30], which exceeds the change observed in this study. The difference may be due to the younger population studied (mean age 28.06, SD 6.06 y), the type of vibration (high-frequency, low-amplitude vibration motors vs 8 Hz solenoid drivers), or the vibration protocol (continuous vs intermittent).

In contrast, this study used a lower frequency (8 Hz) with higher force (20 N free, 9.5 N worn) delivered intermittently (10 s on, 5 min off). This protocol was designed to prioritize safety for older adults and to avoid potential overstimulation. The trade-off may be a slower onset of therapeutic effects, which could require longer intervention periods to detect meaningful changes.

This feasibility study provides the technical foundation for the trial and demonstrates that the device is safe and usable before proceeding to larger controlled studies. Based on descriptive results, we hypothesized mechanisms that require future investigation. The following mechanisms are speculative hypotheses derived from the descriptive findings. They were not directly measured in this study and hence require confirmation through electromyography, neurophysiological, or mechanistic studies. The descriptive pattern of muscle function changes—increased isometric extensor torque but decreased isometric flexor torque, alongside increased isokinetic torque in both muscle groups—might be explained by several hypothetical mechanisms:

1. Reduced antagonistic cocontraction: a decrease in flexor torque during isometric testing might indicate reduced cocontraction of antagonist muscles, which could improve postural efficiency and reduce spinal compressive loads [42]. However, without electromyography data, this remains speculative.
2. Task-specific neuromuscular adaptation: the contrasting results between isometric (flexor torque decrease) and isokinetic (flexor torque increase) tests might suggest that the intervention affects motor control strategies differently depending on the contraction type and speed [43]. This hypothesis requires direct testing.
3. Vibration-induced neural effects: local vibration is known to influence muscle spindle afferents and may alter cortical and spinal excitability [44,45]. These effects could theoretically lead to improved motor unit recruitment efficiency, as suggested by a decreased time to peak torque [46]. However, no neurophysiological measurements were collected in this study.

Future studies should incorporate surface electromyography to quantify agonist-antagonist activation ratios, cocontraction indices, and recruitment patterns during functional tasks. Mechanistic studies using transcranial magnetic stimulation or H-reflex testing are needed to confirm central versus peripheral adaptations.

Limitations

This study has several important limitations as discussed in the following

- Single-participant pilot (phase 3): Only 1 participant completed the 4-week intervention. Therefore, the findings cannot be generalized to the broader population of individuals with hyperkyphosis. Pre-post changes are reported descriptively without inferential statistics (no *P* values, CIs, or effect sizes), as such tests are not valid for N=1.
- No control group: The absence of a control or comparison group means that observed pre-post changes cannot be attributed to the intervention with certainty. Practice effects, natural history, placebo effects, or measurement variability may account for some or all of the observed changes.
- Short intervention duration: Four weeks may be insufficient to detect meaningful changes in spinal alignment, particularly in individuals with mild baseline kyphosis (47.24°). Longer intervention periods (eg, 12 - 24 wk) may be needed for structural spinal changes.
- No mechanistic measurements: electromyography, neurophysiological (H-reflex, transcranial magnetic stimulation), or imaging studies were not conducted. Therefore, the proposed mechanisms involving

cocontraction, motor unit recruitment, or neural adaptation remain speculative and should be interpreted as hypotheses requiring future testing.
- Modest kyphosis change: The 1.43° reduction in TKA did not exceed the MDC (4.62°), indicating that this change was not clinically meaningful. This finding should not be interpreted as evidence of clinical effectiveness.
- Single site, single orthotist: All assessments and fittings were conducted by the same research team at one institution, which may limit reproducibility and generalizability.
- Participant selection: Phase 2 participants (N=10) had a mean age of 62.2 (SD 7.83; range 45 - 77) years and a mean kyphosis of 55.53° (SD 1.69°). The phase 3 participant was 45 years old with milder kyphosis (47.24°), limiting the applicability to older adults or those with more severe hyperkyphosis. Outcomes were assessed immediately after the 4-week intervention. The durability of any observed changes and long-term safety remain unknown.

Clinical Implications (Preliminary)

At present, this device should be considered an investigational tool rather than a clinically proven intervention. Based on this feasibility study alone, the orthosis cannot be recommended for clinical use to improve kyphosis angle or trunk muscle strength. The primary contributions of this study are as follows: (1) demonstrating that a programmable vibration system can be successfully integrated into a semirigid spinal orthosis, (2) providing bench-tested technical specifications, and (3) establishing preliminary safety and adherence data to justify larger controlled trials. Clinicians and researchers may use these findings to guide the design of future studies but should not interpret the descriptive pre-post changes as evidence of clinical effectiveness.

Conclusion

A semirigid thoracolumbar orthosis with integrated programmable vibration (8 Hz, 20 N free force, 9.5 N/cm² on-body contact pressure) was successfully developed and tested. Bench testing confirmed reliable technical performance. Short-term assessment in 10 participants with hyperkyphosis indicated acceptable comfort and appearance (scores 7.6 - 7.95 out of 10), with no immediate skin safety concerns. In a 4-week single-participant pilot, adherence was 100%, daily wear time met the prescribed target (mean 1.4, SD 0.3 h), and no adverse events were reported. The observed 1.43° reduction in TKA did not exceed the MDC (4.62°) and, therefore, was not clinically meaningful. Descriptive pre-post changes in muscle function outcomes (eg, isokinetic peak torque increases of 8 - 14 Nm) are reported but cannot be attributed to the intervention without a control group or inferential statistics. This study demonstrates technical feasibility and safety, justifying progression to larger controlled studies with adequate sample sizes, control groups, and mechanistic measurements (eg, electromyography) to determine whether this device improves clinical outcomes in hyperkyphosis.

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The responsibility of the final manuscript lies entirely with the authors. GAI tools are not listed as authors and do not bear responsibility for the final outcomes.

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Authors' Contributions

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Formal analysis: FK, MA, SB
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Investigation: FK, MA
Methodology: FK, MA, SB
Project administration: FK, MA
Resources: FK, MA
Software: FK, SB
Supervision: MA, SB
Validation: SB
Visualization: FK, MA, SB
Writing – original draft: FK
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Conflicts of Interest

None declared.

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ABBREVIATIONS

AISI: American Iron and Steel Institute
MDC: minimal detectable change
TKA: thoracic kyphosis angle

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Conceptual Model for the Integration of Marketing Strategies and Biomedical Innovation in Patient-Centered Care: Mixed Methods Study

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Abstract

Background: The increasing integration of biomedical technology and digital marketing is quickly transforming how patients engage with health care. The patient as an organization (PAO) model is explored in this study. The PAO model encourages patients to be active participants in health care decisions by leveraging wearables, mobile health (mHealth) apps, artificial intelligence (AI) platforms, and health care marketing strategies.

Objective: This study aims to examine how the PAO model is evolving in practice and gain insight into both the opportunities and challenges created by the intersection of biomedical innovation and marketing practices in patient care.

Methods: The scoping review was conducted across Scopus, Web of Science, PubMed, and Google Scholar. Selection criteria included articles published from 2014 to 2024. Studies were included if they examined connections among biomedical technologies, marketing strategies, and models of behavior and organizations. Studies lacking interdisciplinary focus or methodological rigor were excluded. Since this work was exploratory, it did not require a strict bias assessment. Additionally, findings derived from qualitative analysis of 18 semistructured interviews with patients, health care professionals, and technologists regarding their experiences with digital technologies and perceptions of trust, autonomy, and engagement were analyzed. Thematic analysis was applied to these interviews using open, axial, and selective coding.

Results: From an initial pool of 22,740 records, 45 studies met the inclusion criteria and were analyzed. The review revealed that the integration of AI-based personalization, biosensors, and remote monitoring with marketing strategies, such as segmentation, customer relationship management systems, and behavioral nudging, offers potential to enhance patient autonomy and engagement. However, most studies were descriptive or exploratory, with limited empirical evaluation, particularly regarding ethical risks and digital inequality. Qualitative findings further illustrated how patients are adopting organizational behaviors, such as self-monitoring, real-time decision-making, and strategic management of health data. The following 5 key themes emerged: (1) patients as autonomous digital actors, (2) digital health as a behavioral ecosystem, (3) inequities in digital empowerment, (4) negotiating trust and ethical transparency, and (5) blended care as the preferred future. Although many participants embraced digital tools, concerns about data transparency, algorithmic bias, and loss of human connection highlighted important barriers to equitable adoption.

Conclusions: The PAO model shows strong potential for personalizing care and engaging patients in health care. However, it is important to note that, so far, conceptual models have dominated the PAO literature, with little empirical evidence to support them. Therefore, as health care practices increasingly integrate digital technologies, it is crucial to develop appropriate safeguards for PAO models.

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KEYWORDS

biomedical technology; patient engagement; digital health; AI in health care; health marketing; wearables; CRM; customer relationship management

Introduction

The concept of the patient as an organization (PAO) marks a significant shift in digital health care, redefining the patient as an active participant, strategic decision-maker, and key stakeholder in their care. Instead of being passive recipients of treatment, patients are increasingly managing their health data, engaging with providers, and shaping the design of the health care system. Based on organizational theory and health care strategy, this model encourages patients to take on roles typically

held by structured entities, emphasizing self-management, participation, and governance. The World Health Organization (WHO) has recognized this change, calling for greater patient involvement in the development and implementation of health care systems to promote more responsive and effective care [1].

Despite its increasing importance, the PAO model remains mainly theoretical. Although benefits such as better health outcomes, lower system costs, and increased patient satisfaction are often cited, most practical efforts focus on mobile apps and wearable devices. However, truly decentralized health care, another major shift, depends on broader technological integration. Future systems will need to incorporate artificial intelligence (AI)–powered diagnostics, big data analysis, home-connected medical devices, and generative AI platforms such as ChatGPT [2]. These tools are not just extras; they change how health care is delivered, expanded, and customized.

Currently, patient-centered care tends to focus heavily on disease management. However, health care should encompass more than that: It should include wellness promotion, behavioral support, and preventive care [3]. This broader approach reflects a shift from reactive, "disease-care" models toward proactive, wellness-oriented digital health systems. The expanding role of mobile and digital platforms in areas like fitness tracking, lifestyle coaching, and preventive screening reflects this growth, creating not only new models of care but also new opportunities for health business innovation [4].

Within the PAO framework, the patient becomes a digitally connected and ethically engaged actor, actively managing their health records, co-designing service delivery, and even contributing to policymaking and research. This reframing introduces new dimensions of trust, transparency, and autonomy. It also brings the patient experience closer to the structure of advocacy-driven nonprofit organizations that represent patient and caregiver interests. However, trust is not simply a desirable outcome; it is essential, and yet, the ethical dimensions of digital health marketing, including privacy, consent, and algorithmic bias, are often underexplored [5].

The adoption of technology in health care has grown rapidly. More than 50% of patients now use telemedicine, more than 90% of care providers utilize electronic health records, and digital platforms such as social media are commonly used for health communication. However, these advances often mask ongoing digital inequalities along lines of race, geography, income, and education [6]. To address this, health care organizations should learn from business, particularly in behavioral segmentation, predictive analytics, and customer relationship management (CRM). Strategic planning and customized communication are crucial for expanding access, increasing reach, and improving health outcomes.

At the heart of this transformation lies biomedical technology: a fusion of biology, engineering, and computing designed to enhance care across the continuum. AI-powered imaging tools, biosensors, implantable monitors, and smart prosthetics now enable real-time diagnostics, adaptive treatment, and precision health management [7]. Examples include robotic-assisted surgeries that reduce risk, insulin pumps that automatically respond to glucose fluctuations, and wearable devices that track behavior and symptoms in real time, bridging gaps in traditional health care.

These technologies demand parallel evolution in data governance, security, and ethics. Management leaders must ensure that AI-powered systems comply with privacy regulations, cybersecurity frameworks, and inclusive design principles. The WHO's *Global Strategy on Digital Health 2020 - 2025* reinforces this direction, advocating for equity-focused digital transformation, especially in resource-constrained regions.

The PAO model is a convergence point, strategically integrating biomedical technology, behavioral science, and health care marketing. It supports a move from static, episodic treatment to dynamic, data-informed, and personalized health care management. Patients are no longer seen simply as users of care; they are empowered collaborators who coproduce health outcomes through technology-enabled engagement and decision-making [8].

Marketing frameworks provide a valuable lens for translating innovation into actionable steps. The traditional 4 Ps of product, price, place, and promotion take on renewed significance in the digital health era: [9]

- Product includes AI diagnostics, wearable biosensors, robotic interventions, and mobile point-of-care tools that support accuracy, personalization, and autonomy [10].
- Price is reflected in value-based care models like pay-for-performance, which reward quality and efficiency enabled through biomedical monitoring [11].
- Place reflects that care is no longer confined to clinical spaces. With portable, internet-connected tools, services can reach patients in their homes, remote regions, or emergency settings [6].
- Promotion through digital communication, including ethically designed AI messaging, social media campaigns, and CRM outreach, ensures that patients receive accurate, timely, and personalized health information [12].

The convergence of digital health technologies with health care delivery not only drives innovation but also supports global health equity. Scalable tools, like mobile diagnostics and cloud-based platforms, can extend care to underserved communities and help reduce disparities.

Although digital tools offer benefits such as improved access, personalized communication, and behavior change, deeper issues, like digital exclusion, ethical concerns, and systemic barriers, remain underexplored. Challenges such as unequal access, low digital literacy, and lack of trust persist, particularly in marginalized populations.

To address these gaps, this study combined a scoping literature review with qualitative research to examine the evolving concept of the PAO. We explored how patients increasingly engage in organizational-like behaviors, such as self-tracking, strategic participation, and co-creating care, while facing barriers related to equity, ethics, and infrastructure.

By grounding the PAO model in interdisciplinary and empirical research, we moved beyond theory to examine how emerging

technologies, like AI tools, wearables, and mobile health (mHealth) apps, are reshaping patient roles. Our goal was to understand how these tools influence patient engagement, decision-making, and autonomy within connected, data-driven health care systems.

Methods

Mixed Methods Design

This study followed a mixed methods design consisting of 2 stages: Stage 1 involved a scoping review of the literature, and stage 2 included a qualitative study using semistructured interviews.

The study design was guided by the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews) framework and informed by constructivist-grounded theory principles to allow for the emergence of themes grounded in real-world patient experience.

Stage 1: Scoping Review Method

Design and Framework

This study used a scoping review methodology guided by the PRISMA-ScR framework to ensure clarity, transparency, and academic rigor [13]. This review examined how biomedical technologies and marketing theory intersect within the emerging PAO model. Using a scoping review approach, we mapped contributions across health care, behavioral science, and management to highlight key insights and gaps. This helped build a clearer picture of how digital tools and health marketing can together support more responsive, data-driven, and patient-centered care.

Search Strategy and Data Sources

To achieve disciplinary depth and interdisciplinary breadth, an exhaustive academic search was conducted across 4 prominent databases: Scopus, Web of Science, PubMed, and Google Scholar. Boolean operators and carefully selected keyword combinations were used to explore the intersections between digital health, biomedical innovation, and health care marketing.

Key terms included *healthcare*, *CRM (Customer Relationship Management)*, *biomedical innovation*, *AI personalization in healthcare*, *digital nudging*, *behavioral economics in healthcare*, *health belief model*, *segmentation*, and *patient targeting*.

Research Questions

Research question (RQ) 1 was “In what ways do patients use biomedical technologies—such as wearables, mHealth apps, and AI-powered tools—to take control of their health and engage in self-management similar to organizational behavior, and how do ethical safeguards and equitable access shape these practices across diverse populations?”

RQ2 was “How are marketing strategies such as personalization, segmentation, and CRM integrated into biomedical technologies to enhance patient engagement, treatment adherence, and behavior change, and what equity and ethical challenges arise in this integration?”

RQ3 was “What social, structural, and contextual factors, such as digital literacy, access to infrastructure, and socioeconomic status, affect patients’ ability to use biomedical technologies effectively and equitably within the PAO framework?”

RQ4 was “How do patients understand and respond to ethical concerns associated with biomedical technologies, including data-driven personalization, algorithmic decision-making, and digital nudging, and how do these perceptions influence trust, autonomy, and willingness to adopt such tools?”

RQ5 was “How is the model of the PAO delivered by way of biomedical technologies, and how can it be conceived and regulated to give priority to equity, inclusiveness, and ethical integrity as core conditions for success?”

Together, these findings indicated that, although the literature offers rich descriptive themes, it often lacks rigorous appraisal of effectiveness and equity, which weakens the PAO model’s empirical foundation. This limitation informed the qualitative phase of this study, designed to provide deeper, evidence-based insights.

Describing How the Scoping Review Informed the Qualitative Phase (From Stage 1 to Stage 2)

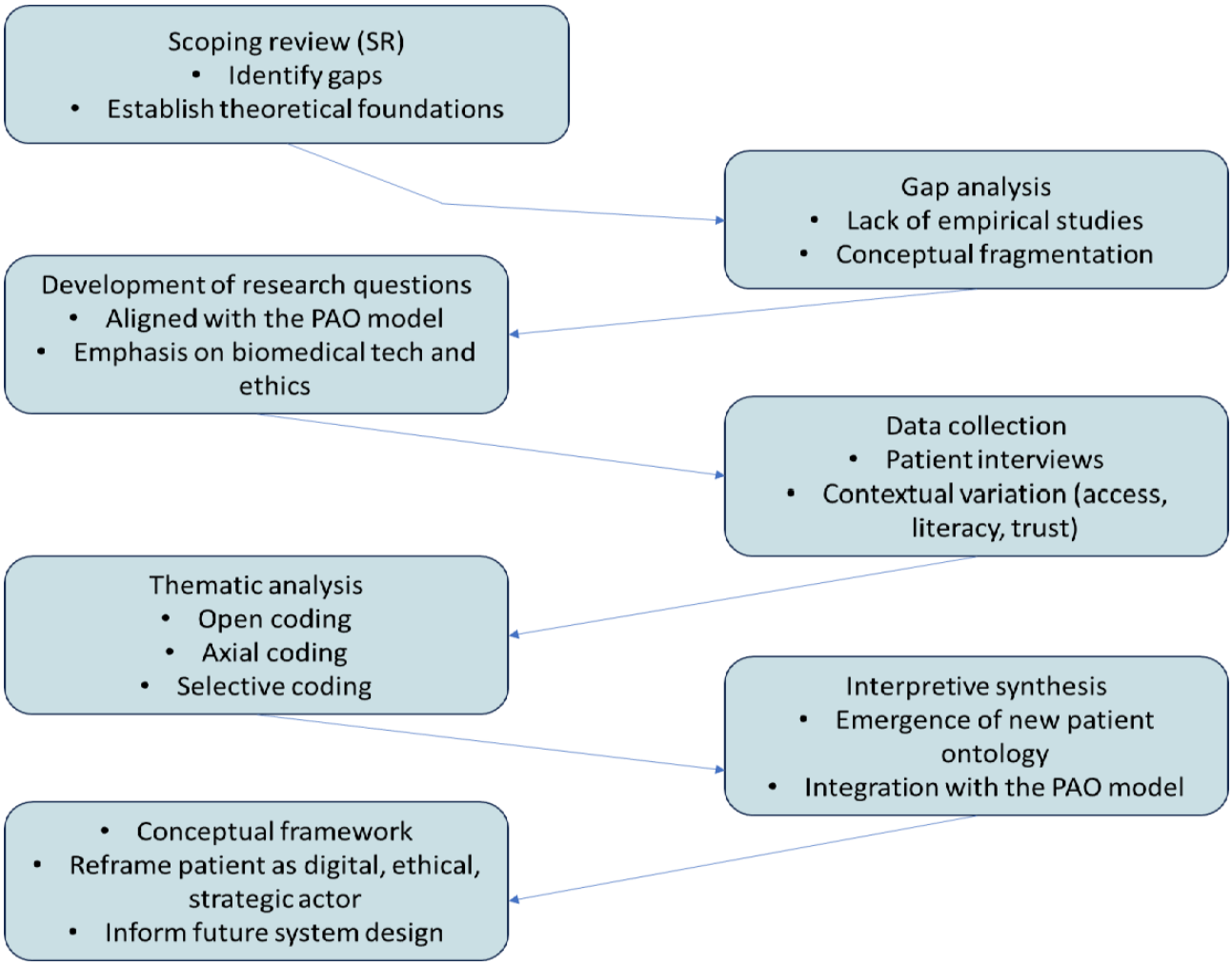
Overview

Although the scoping review offered a strong conceptual foundation, highlighting how digital tools and marketing strategies are shaping a new model of patient engagement, it also revealed important gaps. Many studies were exploratory and lacked insight into how patients in real life experience these innovations. To address this, we turned to the second phase of the study: qualitative interviews. This phase aimed to ground the theoretical potential of the PAO model in the voices and lived experiences of patients, clinicians, and digital health developers. By listening closely to how people interact with technologies in their everyday health routines, we were able to explore how the PAO model is beginning to take shape beyond theory and where its promises meet real-world complexity.

Research Design

Figure 1 illustrates a visual roadmap linking the scoping review to the qualitative phase of this study. The scoping review provided a foundation by highlighting key conceptual gaps, such as the lack of empirical evidence and fragmented definitions of the PAO. These insights directly guided the development of RQs centered on biomedical technology, ethics, and patient empowerment. Based on these questions, qualitative data were collected through in-depth patient interviews, focusing on real-world factors like digital access, literacy, and trust. Using a structured thematic analysis process, including open, axial, and selective coding, patterns that emerged were combined into a coherent framework. This integration of findings not only refined the PAO model but also helped develop a new patient ontology that portrays individuals as active, ethical, and strategic contributors to the future design of health systems.

Figure 1. Methodological flowchart for developing and synthesizing the patient as an organization (PAO) conceptual framework based on the authors' scoping synthesis and principles of qualitative research design.



Stage 2: Qualitative Study Method

Overview

The qualitative study aimed to explore how patients, health care professionals, and biomedical technologists experience the integration of digital tools and marketing strategies in health care. Although the sample size (n=18) may seem small, it was intentionally chosen to align with the study's exploratory goals and to prioritize conceptual depth and theoretical insight. Participants were purposively selected from 3 stakeholder groups to ensure diversity in experience, role, and digital exposure. Saturation was reached after 12 interviews, with additional participants confirming the existing themes rather than adding new ones. Beyond saturation, the adequacy of the sample is supported by the richness and variation in responses, which provided enough depth to identify recurring themes related to autonomy, trust, digital exclusion, and the changing role of the patient. The study prioritized analytical depth over statistical breadth, aligning with qualitative methods that focus on developing conceptual frameworks rather than producing generalizable results. Furthermore, because the study's goal was to refine the emerging PAO model and examine its real-world applications, this approach enabled a layered, interpretive analysis of how digital tools influence patient behavior and engagement. Nonetheless, broader claims about the model's applicability will require further empirical testing across larger, more diverse populations.

Qualitative Research Design

In today's evolving health care ecosystem, the PAO concept lies at the center of transformation, shaped by advancements in biomedical technologies and strategic health care marketing approaches [14]. Marketing plays a crucial role in influencing how patients perceive, adopt, and integrate such technologies into their daily self-care routines [15]. However, adoption remains a nuanced process, shaped by factors such as technological trust, usability, privacy concerns, digital literacy, and the demand for accessible and personalized solutions.

This qualitative study was designed to explore the lived experiences of patients, health care providers, and biomedical technologists to understand the interplay between patient empowerment, biomedical innovation, and health care marketing strategies. Specifically, it sought to examine the facilitators and barriers to adoption of digital health technologies and identify how marketing can be aligned with the values and expectations of technologically enabled, self-managing patient communities.

Participants and Sampling

Participants were recruited using purposive sampling to ensure that they were relevant to the research focus. The inclusion

criteria required participants to have a minimum of 1 year of experience using or developing digital health technologies, such as wearable biosensors, mHealth apps, or AI-powered tools. Participants represented 3 stakeholder groups: patients actively using digital tools, health care professionals implementing these technologies, and biomedical technologists involved in the design and deployment of these technologies. Individuals with no relevant experience or those unable to provide informed consent were excluded from the study.

Data Collection

We conducted 18 semistructured interviews using secure online video conferencing platforms to facilitate accessibility and geographic diversity. Each interview lasted between 45 minutes and 60 minutes and was audio-recorded with participant consent. The interview protocol included open-ended questions designed to elicit insights into technology adoption behaviors, trust dynamics, usability experiences, marketing communication preferences, and ethical concerns.

Data Analysis

The study used a grounded theory–inspired coding process, comprising open, axial, and selective coding, to identify patterns and themes within the data [16]. Interviews were transcribed verbatim and analyzed iteratively using qualitative analysis software. Thematic saturation was reached after 12 interviews, at which point adding new data no longer yielded novel insights. Consistent with the *Law of Diminishing Returns in Qualitative Research* [17], data collection ceased at this point to maintain methodological efficiency and thematic clarity.

This approach ensured that each interview contributed meaningfully to understanding how patient organizations engage with digital tools, what shapes their decision-making, and how biomedical solutions can be better aligned with trust, values, and behavioral drivers.

Ethical Considerations

The study was conducted in accordance with ethical guidelines for qualitative research. All participants provided informed consent. Data were anonymized, securely stored, and used solely for research purposes. Because the interviews were conducted for academic purposes only and will not be used for commercial or promotional purposes, review by an institutional review board was not required [18-20].

Results

Stage 1: Scoping Review Results

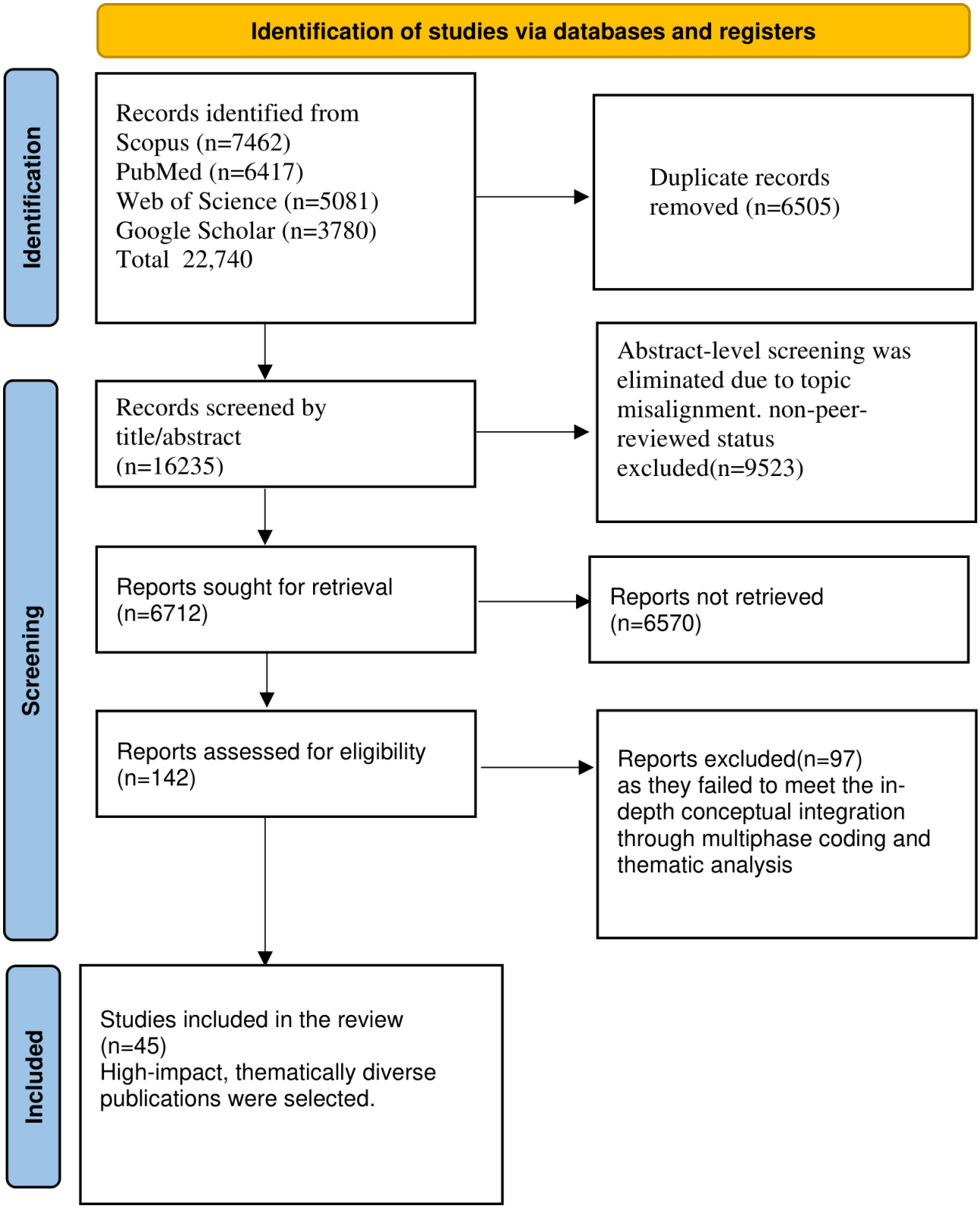
Mapping the PAO Landscape

The search process yielded a total of 22,740 records (Scopus: n=7462; Web of Science: n=5081; PubMed: n=6417; and Google Scholar: n=3780). Following the removal of 6505 duplicate entries, 16,235 unique records remained for initial screening. Abstract-level review excluded 9523 studies due to topic misalignment, lack of peer review, or language barriers. The remaining 6712 full-text articles were assessed for methodological quality and thematic alignment.

Of these, 142 studies met the inclusion criteria for the qualitative synthesis. However, 97 were excluded during deeper analysis because they lacked the conceptual integration required by the multiphase coding framework. Ultimately, 45 high-impact and thematically diverse publications were selected for inclusion.

This entire process adhered to the PRISMA-ScR guidelines and is visually summarized in Figure 2, which outlines the identification, screening, eligibility, and inclusion phases of the review.

Figure 2. PRISMA-ScR (Preferred Reporting Items for Scoping Reviews and Meta-Analyses Extension for Scoping Reviews) flow diagram [21].



Scoping Review Findings: Mapping Biomedical and Marketing Integration Within the PAO Model

From over 22,000 records, the scoping review identified 45 key studies exploring how biomedical innovation intersects with health care marketing under the PAO model. Common themes included AI-driven segmentation, behavioral economics, CRM, and digital nudging, highlighting new ways to personalize care and boost patient engagement. Many studies also pointed to the growing use of wearables, biosensors, and mHealth platforms to support real-time feedback and predictive analytics.

However, the evidence was uneven. Most research was exploratory, based on small pilot studies or case studies, with few rigorous evaluations or long-term outcomes. Promising tools such as AI segmentation and CRM often failed to account

for cultural, ethical, or trust-related factors. Digital nudging raised concerns around autonomy, but few studies tested its real-world impact.

In short, although the PAO model shows strong potential, its practical value is still emerging. Clearer evidence and stronger ethical frameworks are needed to turn these innovations into scalable, patient-centered solutions.

Three Core Themes Emerged Across the Literature

AI-Driven Personalization and Segmentation

Many studies examined how AI and predictive analytics are used to tailor interventions to individual health profiles. These approaches mirror commercial segmentation strategies, enabling more responsive, targeted care.

CRM and Engagement

The adaptation of CRM systems in health care is enabling more continuous and personalized communication between patients and providers. This has shown promise in improving satisfaction, adherence, and long-term engagement.

Digital Nudging and Behavioral Influence

Several articles discussed the use of behavioral nudges embedded in apps and digital platforms to encourage healthier choices. However, concerns around autonomy and the ethical boundaries of persuasive design were rarely explored in depth.

Gaps in the Evidence Base

In addition to these thematic strengths, the review also highlighted important gaps in the current evidence base. Most studies were exploratory, drawing on pilot projects, descriptive analyses, or commercial analogies rather than longitudinal evaluations or controlled trials. Empirical testing of effectiveness, ethical risks, and digital equity was limited, particularly regarding diverse patient representation and co-designed solutions. Issues like data transparency, algorithmic bias, and unequal access to technology received minimal attention.

Despite these limitations, the review provided a rich conceptual foundation for understanding how the PAO model is developing. It also helped guide the qualitative phase of the study by identifying key mechanisms such as personalization, behavioral design, and engagement technologies through which patients are increasingly acting as strategic, data-informed participants in their care.

Stage 2: Qualitative Findings—Patients as Self-Organizing Actors

Participant Overview

Interviews took place with 18 participants who had direct and indirect experience with patients and represented clinicians and digital health technology experts. The participants had various experiences with technologies such as AI-based health applications and patient portals.

Exploring Patient Experiences With Biomedical Technologies Through the PAO Lens

Table 1 shows how patient experiences and stakeholder insights informed the conceptual development of the PAO model across behavioral, ethical, structural, and systemic dimensions by mapping RQ1-RQ5 to the thematic categories that emerged during the qualitative analysis.

Table . Alignment of interview themes with corresponding research questions (RQs) in the patient as an organization (PAO) framework, developed by the authors based on thematic analysis of qualitative interview data.

Interview question	Related theme
RQ1	Patients as autonomous digital actors
RQ2	Digital health as a behavioral ecosystem
RQ3	Inequities in digital empowerment
RQ4	Trust and ethical transparency
RQ5	Blended care and systems-level PAO framework

How Do Patients Describe Their Experiences With Biomedical Technologies (eg, Wearables, Health Apps, AI Tools) for Monitoring, Managing, and Making Decisions About Their Health?

This explored self-regulation, autonomy, and organizational behaviors from the patient's perspective. The interview focus was on "How do you use digital tools to track or manage your health? What role do these tools play in your decision-making?"

In What Ways Do Patients Perceive That Digital Health Platforms Apply Personalization, Nudging, or Targeted Communication Strategies to Influence Their Health Behaviors?

This investigated how marketing strategies are experienced through biomedical technology (eg, STP, CRM, and behavioral nudging). The interview focus was on "Do your apps or tools provide personalized suggestions or reminders? How do these affect your motivation or trust?"

What Challenges Do Patients Face With Accessing, Understanding, and Effectively Using Biomedical Technologies, Particularly Across Socioeconomic or Geographic Contexts?

This addressed the digital divide, equity, and structural limitations to PAO operationalization. The interview focus was on "What makes it easy or difficult for you to use digital health

tools? How do factors like internet access or digital literacy impact your experience?"

How Do Patients View Consent, Data Privacy, and Transparency Issues When Interacting With AI-Powered or Data-Driven Biomedical Tools?

This explored ethical concerns tied to trust, data handling, and algorithmic personalization. The interview focus was on "How do your apps or devices use your health data? How does this affect your trust in the system?"

How Do Patients Envision the Ideal Balance Between Digital Technology and Human Interaction in Health Care, and What Features Do They Believe a Future Digital Health System Should Include?

This aimed to co-create or inform a future interdisciplinary PAO framework. The interview focus was on "How do you feel about relying on technology versus speaking with a health care provider? What would your ideal digital health system look like?"

Understanding the Operationalization of the PAO Model

Thematic Analysis

Thematic analysis of the qualitative interviews uncovered a set of interconnected themes that demonstrate how patients are increasingly adopting organizational-like roles within digital health ecosystems [22]. These themes corresponded to the core pillars of the PAO framework, specifically behavioral agency, digital engagement, structural equity, ethical trust, and systems-level integration.

As shown in Table 2, each theme was closely aligned with one of the core RQs (RQ1–RQ5), demonstrating how participants' lived experiences reflect the evolving roles of patients as autonomous decision-makers, digital collaborators, and ethical stakeholders. From personalized technology use and behavioral self-regulation to trust in AI-driven tools and systemic challenges in access, the findings provide a nuanced understanding of how the PAO model is being enacted in real-world contexts.

Table . Thematic evaluation of biomedical technology within the patient as an organization (PAO) framework based on a thematic synthesis of selected literature in the scoping literature review by the authors.

Theme	Key studies (authors, year)	Role of biomedical technology	Critical evaluation	Thematic transition
Segmentation, targeting, and personalization (STP)	Brommels, 2020 [23]	AI[a]-driven segmentation tools and digital health communication platforms support tailored interventions.	Although conceptually strong, most evidence comes from small-scale or single-site pilots. Limited comparative testing undermines PAO's claim to broad applicability and limits scalability.	It provides the foundation for targeted interventions but requires stronger, cross-system validation to serve as a reliable PAO mechanism.
Health belief model (HBM)	Ahadzadeh et al, 2015 [24]	AI-powered symptom checkers and telemedicine platforms tailor communication to patient risk perceptions.	Evidence is effective for literate and digitally fluent users but neglects populations with low health literacy or limited digital access. This exclusion undermines PAO's inclusivity.	It establishes a psychological basis for personalization, but without testing in vulnerable groups, it risks reinforcing inequities within PAO.
Behavioral influence and social marketing	Evans, 2006 [25]	Behavioral analytics and health apps are designed for broad population-level engagement.	This demonstrates strong public health influence, yet applications in chronic care and low-resource contexts remain underexplored. The lack of contextual adaptation limits PAO's scalability.	It informs engagement strategies but remains descriptive; long-term effectiveness must be empirically tested for PAO adoption.
Customer relationship management (CRM)	Mohiuddin, 2019 [26]	Predictive communication tools, EHR[b]-linked messaging, and reminder systems sustain engagement.	Although these are effective for engagement, the evidence draws heavily on commercial analogies. Few longitudinal health care studies exist, leaving CRM's role in PAO sustainability unproven.	It suggests potential for trust-building and continuity but risks oversimplifying health care relationships unless tested in diverse care environments.
Branding and trust-building	Mohamed, 2022 [27]	Transparent design interfaces, ethical AI systems, and privacy protocols support trust.	Although this is conceptually robust, most studies are cross-sectional, offering little insight into how trust evolves. This gap weakens PAO's ethical foundation.	It establishes an ethical entry point for PAO adoption, but without longitudinal studies, it remains more aspirational than practical.
Innovation adoption (diffusion theory)	Dearing and Cox, 2018 [28]	Wearables, telehealth tools, and peer-based adoption stories encourage uptake.	It explains early adoption effectively but overlooks structural barriers for marginalized groups. Evidence is skewed toward digitally privileged populations.	This drives momentum for mainstreaming PAO but requires inclusive adoption models to ensure equity.
Behavioral nudging and economics	Auf et al, 2021 [29]	Gamification, default settings, and subtle interface nudges are embedded in health apps.	These encourage short-term behavior change, yet few real-world studies examine ethical limits in high-stakes care. Weak empirical grounding risks compromising autonomy in PAO.	This supports digital habit formation but needs stronger ethical evaluation to avoid coercion in PAO practices.
Information-motivation-behavioral skills (IMB) model	Rongkavilit et al, 2010 [30]	Decision aids, chatbots, and adaptive mobile learning systems build skills and motivation.	It shows strong empowerment potential but most evidence comes from youth or disease-specific contexts (eg, HIV). Broader transferability has not been tested, limiting PAO's reach.	It bridges education and empowerment but requires validation in chronic and multimorbidity settings for PAO credibility.

Theme	Key studies (authors, year)	Role of biomedical technology	Critical evaluation	Thematic transition
Patient empowerment and co-creation	Vainauskienė and Vaitkienė, 2021 [31]	Real-time feedback dashboards and participatory design platforms encourage collaborative care.	This demonstrates high potential for co-design, but most applications are exploratory or conceptual. Lack of real-world implementation reduces PAO's structural legitimacy.	It completes the feedback loop for PAO but risks tokenism without evidence of genuine patient integration into decision-making.

[a]AI: artificial intelligence.

[b]EHR: electronic health record.

Patient-as-Agent: Emergence of Self-Regulation and Decision-Making

Participants consistently described themselves as "managers" of their health, citing wearables, symptom trackers, and health apps as tools that extend their decision-making processes. They reported scheduling appointments, adjusting lifestyle behaviors, and even questioning clinical advice based on insights derived from digital devices. This reflects a shift toward self-regulation, where patients assume roles once reserved for organizational actors, such as analysts, strategists, and communicators.

> *My smartwatch alerts me when my heart rate spikes, and I've learned to adjust my pace or diet accordingly. It feels like having a personal assistant, but ultimately, I take the final decision.* [Participant 11, age 65 years, rural man, retired government officer]

Digital Health as a Marketing System: Engagement, Nudging, and Feedback Loops

The integration of marketing concepts, particularly segmentation, nudging, and personalization, was evident in how participants responded to app interfaces and notifications. Many acknowledged that gamified elements, personalized reminders, and visual dashboards were crucial for sustaining motivation. However, responses also revealed ethical ambivalence: Although participants appreciated targeted support, they expressed concerns about potential manipulation and the use of data.

> *The app rewards me for reaching my step goals, but I often question how it uses my data. Is it genuinely assisting or trying to sell me something?* [Participant 10, age 30 years, urban woman, renowned corporate figure]

Digital Exclusion and Structural Constraints

Despite enthusiasm for digital tools, disparities were evident. Participants from lower socioeconomic backgrounds or remote locations reported limited access, connectivity challenges, and difficulties navigating complex interfaces. Older participants often lacked digital literacy or felt overwhelmed by "data overload." This highlights the digital divide and the need for inclusive design.

> *The hospital I visited in Delhi told me to use the app, but I don't have Wi-Fi at home. And when I try to use it, it's too confusing. I stop.* [Participant 18, age 55 years, rural woman, school teacher]

Trust and Transparency in AI and Personalization

Participants articulated trust as both a prerequisite and an outcome of digital health interaction. When transparently delivered, personalized care enhanced patients' perception of safety and value. However, algorithmic opacity and inconsistent recommendations undermined confidence. Many desired "explainable AI" and clearer data use policies.

> *If I knew the logic of how it decides what to show me or suggest, I would trust it more. However, it feels like a black box right now.* [Participant 2, age 40 years, urban man, real estate businessman]

Need for Human Touch Amid Digital Expansion

Although digital interfaces were valued for convenience and personalization, patients emphasized the irreplaceable value of human connection. Participants advocated for blended care models where technology augments clinician relationships but does not replace them.

> *I appreciate the app, but I prefer a human to explain serious issues rather than a chatbot.* [Participant 6, age 53 years, suburban woman, homemaker]

Thematic Coding Framework: Operationalizing the PAO Model in Digital Health

To explore how the PAO model is unfolding in real life, we used a 3-step coding process rooted in constructivist-grounded theory. This approach helped us make sense of recurring patterns in what participants shared during interviews.

In the first stage (open coding), we identified specific behaviors and concerns—things like self-tracking habits, reactions to AI-driven personalization, responses to digital nudges, and worries about data privacy and trust (see Table 3). Commercial analogies helped illustrate the PAO model by translating strategies from retail, tech, and service industries to the individual patient level. These comparisons offer fresh perspectives on personalization, engagement, and collaboration, but their nonclinical origins highlight the need for stronger validation within health care settings.

Table . Commercial analogies in the patient as an organization (PAO) model developed by the authors drawing on practices from Amazon, Apple, IKEA, Netflix, and loyalty or supply chain models to illustrate conceptual parallels in the PAO framework.

Commercial practice	Application in the PAO model	What it offers	What it misses
Retail segmentation (eg, Amazon product recommendations)	AI[a]-driven patient segmentation using health and behavioral data to personalize interventions	Tailors care in real time, making treatment more responsive	It risks oversimplifying complex patient needs, and potential for algorithmic bias exists.
Customer loyalty programs (eg, airline frequent flyer, hotel rewards)	Health care CRM[b] platforms that predict adherence and personalize communication	Builds long-term engagement and strengthens patient-provider relationships	Patients are not "customers"—trust in care requires ethical accountability, not just loyalty.
Digital nudging (eg, Netflix autoplay, app notifications)	Health nudges in apps prompting exercise, diet, or medication adherence	Encourages healthy habits and sustained engagement	It may compromise autonomy if patients feel manipulated rather than supported.
Co-creation in services (eg, IKEA design input, open-source platforms)	Participatory health platforms where patients co-design care plans and give feedback	Empowers patients as partners and fosters collaboration	Access barriers and digital literacy gaps may exclude vulnerable populations.
Branding in consumer tech (eg, Apple's design and trust strategy)	Branding of digital health platforms to foster confidence and ease of use	Reduces anxiety and encourages adoption	Trust in health care must rest on transparency, fairness, and safety, not just design.
Supply chain logistics (eg, just-in-time inventory systems)	Wearables and biosensors providing continuous data for anticipatory care	Prevents crises through early intervention; improves efficiency	It relies on constant connectivity and raises concerns about privacy and governance.

[a]AI: artificial intelligence.

[b]CRM: customer relationship management.

The individual insights shown in Table 3 were then grouped into broader categories during axial coding (Table 4), including themes like digital self-governance, behavioral engagement tools, and trust and ethical friction.

Table . Open coding of everyday experiences with biomedical technology in the patient as an organization (PAO) context, developed by the authors based on qualitative interview data (2025).

Code	Description
Self-tracking	Use of apps or devices to monitor health metrics
Decision autonomy	Making health decisions based on digital feedback
AI[a] personalization	Adjustments based on algorithmic insights
CRM[b]-based reminders	App notifications encouraging health behaviors
Gamification	Points, badges, and visual cues in apps
Behavioral nudging	Subtle prompts guiding patient behavior
Data confusion	Difficulty interpreting or trusting data
Lack of digital access	Limited or no access to the internet or devices
Low digital literacy	Challenges using digital tools due to the skills gap
Patient skepticism	Doubts about data privacy or app motives
Desire for human contact	Preference for in-person over digital interaction
Trust in tech	Confidence in digital tools and recommendations
Transparency concerns	Lack of clarity around data usage and AI processes

[a]AI: artificial intelligence.

[b]CRM: customer relationship management.

Finally, in the selective coding stage, we pulled everything together into 5 core themes (Table 5) that reflect how people are experiencing and adapting to digital health tools: (1) patients as autonomous digital actors, (2) digital health as a behavioral ecosystem, (3) inequities in digital empowerment, (4) negotiating trust and ethical transparency, and (5) blended care as the preferred future. These themes directly address the research's central question: How is the PAO model operationalized in practice through biomedical technology tools, and what are the ethical, behavioral, and structural implications of this shift?

Table . Axial coding, with code families reflecting the patient as an organization (PAO) model and developed from thematic synthesis of interview data by authors (2025).

Code family	Constituent codes
Digital self-governance	Self-tracking, decision autonomy, AI[a] personalization
Behavioral engagement tools	CRM[b]-based reminders, gamification, behavioral nudging
Structural barriers	Lack of digital access, low digital literacy
Trust and ethical friction	Data confusion, patient skepticism, and transparency concerns
Human-digital synergy	Desire for human contact, trust in tech

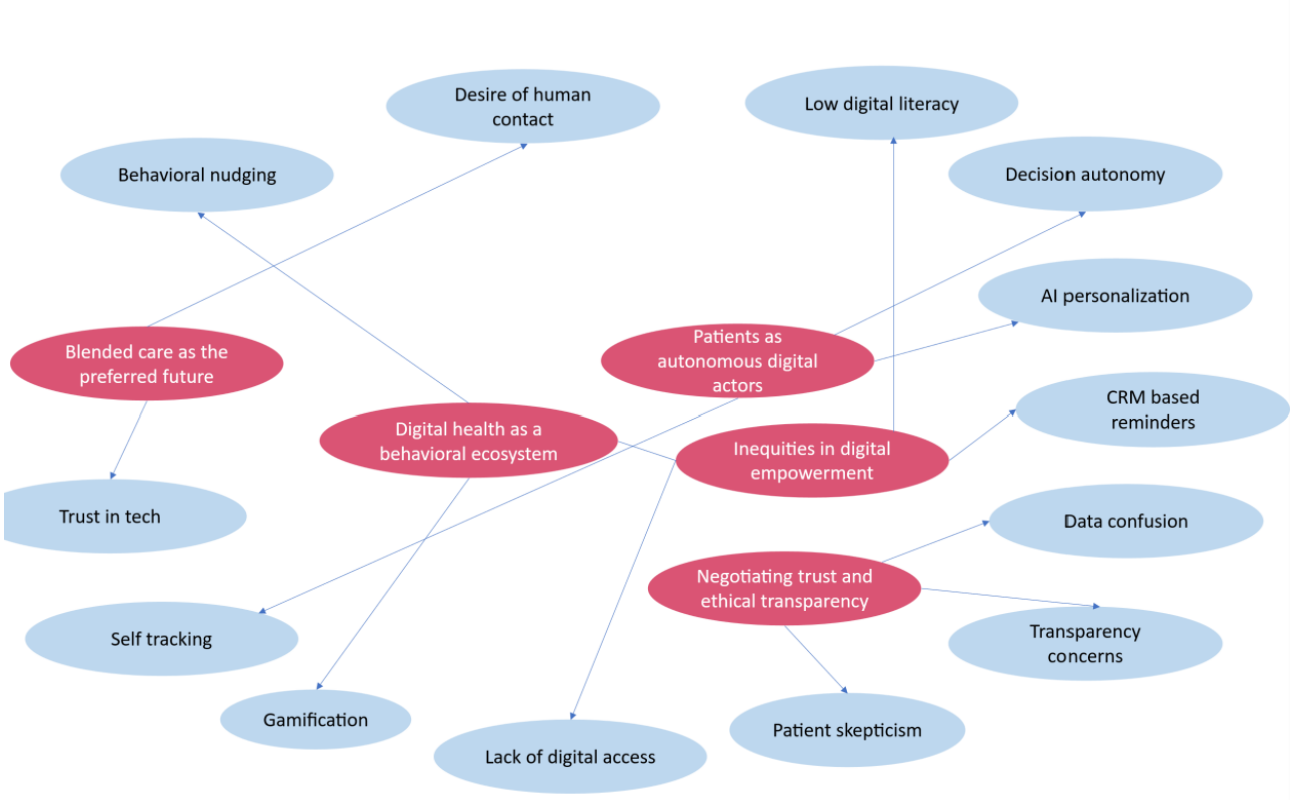
[a]AI: artificial intelligence.

[b]CRM: customer relationship management.

These themes showed how patients are taking a more active role in their care as well as how their experiences are shaped by access, design, trust, and support.

To bring this all to life, Figure 3 maps how individual experiences, like using gamified health apps or struggling with digital literacy, connect to the bigger picture. It visually traces how personal interactions with technology shape and are shaped by the evolving roles patients are playing in today's health care systems.

Figure 3. This code tree, conceptualized by the authors, outlines key patient-centered challenges and themes that shape the digital health experience and documents how individuals interact with emerging technology, the obstacles they face, and the ethical concerns that influence trust and adoption in diverse health care settings. AI: artificial intelligence; CRM: customer relationship management.



This thematic framework grounds the PAO model in real-world voices and helps us better understand how digital tools and health strategies are redefining the patient experience (Table 6). The themes directly address the research's central question: How is the PAO model operationalized in practice through biomedical technology tools, and what are the ethical, behavioral, and structural implications of this shift?

Table . Overarching themes and thematic insights linking patient experiences to the patient as an organization (PAO) framework, as developed from thematic synthesis of interview data by the authors (2025).

Theme	Description	Links to PAO model
Patients as autonomous digital actors	Through digital interfaces, patients demonstrate growing self-regulation and strategic behavior, embodying organizational traits such as monitoring, evaluation, and adaptation.	Aligns with PAO's redefinition of the patient as an active agent in their health journey
Digital health as a behavioral ecosystem	Apps, nudges, CRM[a] reminders, and gamification work in tandem to shape sustained patient engagement. These resemble marketing systems and feedback loops.	Reflects the application of marketing theory (STP[b], CRM) within health care
Inequities in digital empowerment	Access to PAO-enabling technologies is uneven, constrained by structural factors such as socioeconomic status, literacy, and infrastructure.	Reveals a key limitation in PAO implementation across diverse populations
Negotiating trust and ethical transparency	Patients demand clarity around data use and AI[c] decisions. Depending on design and communication, digital systems can facilitate and undermine trust.	Essential for the PAO model to evolve into an ethically grounded framework
Blended care as the preferred future	Despite the convenience of digital technology, human interaction remains essential. Patients seek a hybrid model where technology augments, rather than replaces, the human touch.	Supports a flexible PAO model that integrates human empathy with technological precision

[a]CRM: customer relationship management.

[b]STP: segmentation, targeting, and positioning.

[c]AI: artificial intelligence.

The thematic structure provides a grounded, evidence-based map of how patients are beginning to embody organizational behaviors, where friction points exist, and what conditions are necessary for equitable and sustainable transformation.

Visual Key: Linking Raw Data to Core Themes

In the thematic analysis shown in Figure 3, the red circles represent the high-level themes that emerged during selective coding. These themes, such as *patients as autonomous digital actors* and *blended care as the preferred future*, capture the broader conceptual insights that frame how the PAO model is realized in practice.

In contrast, the blue circles reflect the more granular codes identified during open coding. These codes, such as *self-tracking*, *gamification*, and the *lack of digital access*, are grounded in participants' direct experiences and form the foundation of each theme.

Together, the red and blue circles illustrate how concrete participant narratives (blue) were synthesized into overarching patterns of meaning (red), offering a clear line of sight from real-world observations to theoretical insight. This visual structure is central to understanding the layered complexity of the PAO framework.

Thematic Categories (Axial Coding)

Within the data gathered from the interviews, 5 key themes were evident (Table 5).

The first was the use of digital self-governance. Patients took charge of managing their conditions without assistance by using technology to monitor and track progress.

The second, behavioral engagement tools, covered how reminders, gamification, and nudging led to habit development but also posed questions about user autonomy.

Trust and ethical friction represented the third theme. Attitudes to trust and ethical friction ranged from uncertainty about AI decisions to data use concerns and digital manipulation.

Structural barriers, the fourth theme, included problems such as low digital literacy rates, lack of device and internet access, and poor application usability presented challenges to digital tool use.

In the fifth theme, human-digital synergy involved the use of many valuable digital resources but with an emphasis on augmentation rather than replacement in human interaction.

Integration to Core Themes (Selective Coding)

These factors were integrated to form 5 thematic areas (Table 5) giving insight into the practical application of the PAO model: (1) patients as autonomous digital actors, (2) digital health as a behavioral ecosystem, (3) inequities in digital empowerment, (4) negotiating trust and ethical transparency, and (5) blended care as the preferred future.

These 5 themes formed a complex set of understandings about how people interact with digital health care, not only as technology users but also as strategic and emotionally committed actors. The relationships among these themes are shown in Figure 3, which illustrates how lower-level observations (blue nodes) relate to higher-level organizational themes (red nodes). This level of mapping highlights the richness and depth of analysis in this study and how individual experiences are part of a broader trend in organizational behavior.

Discussion

Principal Findings

Defining the Conceptual Boundaries of the Field

This scoping review advanced the PAO model from a metaphor into a strategic framework rooted in biomedical technology, marketing theory, and digital health practice. Rather than viewing patients as passive care recipients, the literature highlights their role as active, data-aware decision-makers who interact with and shape digital health ecosystems.

The PAO model operates across 3 levels. At the *micro level*, patients manage their health using tools such as wearables, apps, and AI-driven feedback to support self-monitoring and daily decision-making. At the *meso level*, marketing strategies, such as CRM, segmentation, and co-creation, structure how patients engage with health care providers and systems. At the *macro level*, broader issues like policy, regulation, and digital equity influence access, trust, and the overall impact of digital health transformation.

Although the model offers a rich, multilayered view of modern health care, it also presents conceptual challenges, particularly around how individual behaviors translate into system-wide change and how societal structures shape personal experiences. Instead of seeing these tensions as limitations, the review positions them as opportunities to refine the model.

By connecting data flows and decision-making across individual, organizational, and societal levels, the PAO framework has the potential to become a cohesive, ethical, and scalable approach to digital health, one that centers the patient while addressing the realities of technology, governance, and equity.

From Static Segmentation to Dynamic Personalization

Segmentation, targeting, and positioning (STP) have long been foundational marketing strategies. In health care, these have evolved using AI-powered segmentation based on real-time physiological and behavioral data. Studies by Brommels [23] and Minvielle et al [32] described how biomedical technologies enable the continuous reclassification of patients into highly personalized cohorts. However, ethical challenges, particularly those related to algorithmic bias and the risks of overpersonalization, remain underexplored.

Repositioning Behavioral Theories Through Technology

To truly connect biomedical technology with marketing in health care, we need more than comparisons; we need a clear, practical framework. Although strategies such as personalization, CRM, and nudging are often paired with tools like AI and wearables, their true impact on patient behavior is rarely examined.

A better path is to combine behavioral models with real-time tech—using tools that respond to patients' habits, motivations, and health concerns. However, this isn't just a design question; it's an ethical one too. When does a helpful nudge become manipulation?

For the PAO model to be meaningful, it must do more than describe trends. It should explain how these elements work together in everyday care and ensure that technology supports, rather than controls, the patient experience.

Rethinking CRM for a Nonlinear Health Journey

CRM models, which have traditionally been used to foster patient loyalty, now need to adapt to fluid, episodic, and context-driven interactions. Biomedical tools, such as mobile diagnostics and predictive analytics, generate nonlinear touchpoints that challenge traditional CRM funnels [25]. Although CRM provides useful tools for long-term engagement, many studies rely heavily on commercial analogies, neglecting health care–specific factors such as emotional trust, reactions to medical errors, and the maintenance of continuity of care during crises.

Digital Branding and Trust as Ethical Infrastructure

Trust in digital health systems goes beyond user experience; it is built on transparency, data sovereignty, and clarity in algorithmic operations. Mohamed [27] emphasized that branding must now communicate not only usability but also ethical intent. However, most studies treat trust as an outcome rather than a process. There is a need for more in-depth, culturally responsive frameworks that examine how trust develops across various social and institutional contexts.

Adoption Beyond Early Adopters

Innovation adoption is often interpreted through the lens of early adopters, but this perspective overlooks the systemic factors that lead certain populations to resist digital health tools [33]. These include limited infrastructure, historical mistrust, and mismatched cultural values. The existing literature lacks a pluralistic adoption model that reflects the social, historical, and geographic nuances that influence adoption behavior.

The Ethical Ambiguity of Nudging

The conceptual model often presents digital tools, such as AI platforms, wearables, and CRM systems, as if they will inherently empower patients, foster engagement, and enhance autonomy. Although these technologies hold great promise, including personalized care, deeper engagement, and patient co-creation, this view risks overlooking important challenges, including bias, inequality, and subtle forms of coercion (Table 7). Patients may experience technology fatigue, struggle with data misinterpretation, or face structural inequities that limit access and benefits. At the same time, behavioral economics and nudging strategies, though effective in shaping healthier choices, blur the line between ethical persuasion and unintended coercion. In high-stakes health contexts, design elements intended to encourage positive behaviors can inadvertently pressure or manipulate patients, undermining trust. However, few studies critically distinguish between user-centered design that supports autonomy and subtle mechanisms of control that erode it. For the PAO model to develop into a strong framework, it must include a more balanced view—one that recognizes both the potential of digital tools and the ethical and structural risks they pose. This balance will be key for creating frameworks that empower patients without sacrificing ethical safeguards, equitable access, agency, or trust.

Table . Empowering potential and risks of digital tools in the patient as an organization (PAO) model, as developed by the authors based on concepts from digital health, behavioral economics, and health care marketing literature.

Digital tools or strategies	Potential benefits	Associated risks
AI[a] platforms and predictive analytics	Deliver personalized recommendations, enable anticipatory care, and support clinical decision-making	Risk of algorithmic bias, misinterpretation of complex data, and over-reliance on automated outputs
Wearables and biosensors	Provide real-time monitoring, support self-management, and allow early detection of health concerns	Can lead to technology fatigue, data overload, and unequal access due to cost or connectivity
CRM[b] systems in health care	Strengthen patient-provider relationships, tailor communication, and encourage proactive engagement	May reduce patients to "customers," raise privacy concerns, or foster dependency on system-generated prompts
Digital nudging and behavioral economics	Encourage healthier behaviors, improve adherence, and reinforce positive routines	Raise ethical concerns about manipulation, risk of coercion in high-stakes decisions, and potential erosion of autonomy
Participatory platforms and co-creation	Promote shared decision-making, build trust, and empower patients as partners in care	Digital literacy gaps, exclusion of marginalized groups, and uneven levels of participation

[a]AI: artificial intelligence.

[b]CRM: customer relationship management.

From Information to Empowerment: Revisiting the Information-Motivation-Behavioral Skills Model

The information-motivation-behavioral skills (IMB) model is evolving from an educational tool into an empowerment framework, supported by AI-driven guidance systems, decision aids, and adaptive learning tools [30]. However, questions persist: Who determines which information is relevant? How is motivation culturally constructed?

There is a need for more critical, reflexive research that challenges normative assumptions about information delivery and authority.

Feedback and Co-Creation: From Input to Shared Power

Co-creation platforms and feedback mechanisms are central to participatory health care, but many current models stop at surface-level input. Without mechanisms for integrating patient feedback into system design and decision-making, participation risks becoming symbolic [31]. Few studies distinguish between procedural engagement and substantive influence, leaving a gap in conceptualizing truly collaborative health systems.

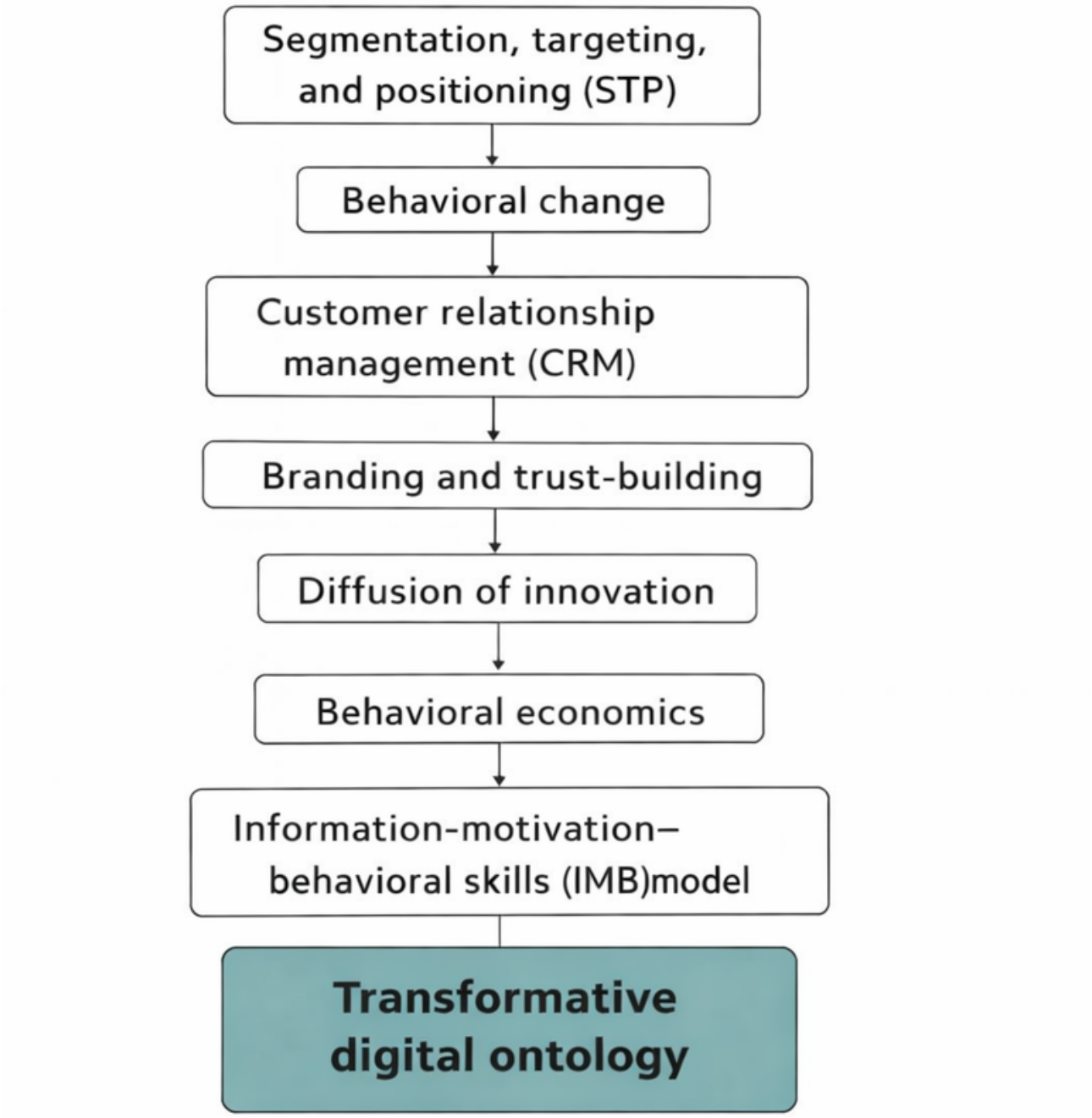
Together, these insights suggest a paradigmatic shift in how we define and interact with the digital patient. The PAO model, when fully realized, reframes the patient as a co-manager, system shaper, and strategic partner in care. This review clarifies the field's theoretical boundaries and proposes an interdisciplinary foundation integrating biomedical engineering, ethical marketing, behavioral science, and patient co-agency. As the digital health landscape continues to evolve, this lens provides researchers, designers, and policymakers with a critical roadmap for developing ethical, inclusive, and technologically responsive systems.

Toward a Conceptual Contribution

The PAO model is often described as if individuals could fully take on the roles of structured organizations, overseeing strategy, governance, and operations. Although this metaphor effectively represents patient empowerment, it risks oversimplifying complex realities and may overestimate what patients can do. Unlike formal organizations, patients usually lack dedicated resources, hierarchical leadership, and institutional authority. Without a clearer definition of what "organizational behavior" means at the individual level, the PAO risks becoming more of a rhetorical device than a practical framework.

This synthesis offers an opportunity to rethink the PAO model, not as a collection of marketing ideas but as a transformative digital framework. As shown in Figure 4, this new approach builds on a step-by-step integration of segmentation, trust-building, behavioral economics, and co-creation strategies, culminating in the development of a transformative digital ontology. Together, these mechanisms change the patient's role from a passive recipient of care to an active, data-informed participant in health care ecosystems. Biomedical technologies are central to this shift: By combining data, autonomy, and organizational logic, they redefine what it means to be a "patient," creating new forms of digital identity that are both empowered and connected [34].

Figure 4. Sequential integration of marketing theories into the patient as an organization (PAO) framework, working toward a conceptual contribution of the patient as a strategic, participatory actor within a dynamic digital health ecosystem and based on the authors' thematic synthesis of literature included in the scoping literature review.



It is important to recognize that the shift toward the PAO model is not equally accessible to all. How patients engage with digital tools is shaped by power dynamics, design decisions, access gaps, and governance structures. Acknowledging these realities does not weaken the PAO concept—it strengthens it by promoting a more inclusive and critical approach to digital health. To advance the field, research must move beyond idealized visions and explore how these dynamics play out in practice. A critical digital health perspective is essential: one that asks what technologies do, what kinds of patient roles they create, and who truly benefits. Rather than undermining the PAO model, this approach ensures it evolves ethically and equitably, with patient trust at its core. By embracing both its potential and its limitations, the PAO model can become a meaningful framework to guiding the future of patient-centered digital health care.

Table 2 highlights the potential of biomedical technologies and marketing frameworks to bring the PAO model into practice but also reveals gaps in the evidence.

Inference and Interpretive Insight

These findings demonstrate that the PAO model is somewhat implemented in practice, especially among digitally engaged patients. However, its application varies and is contingent on access, literacy, trust, and ethical clarity. Although digital tools are starting to promote organizational behaviors, such as self-monitoring, treated responses based on segmentation, and

adaptations driven by feedback, they are primarily effective within privileged structures [35].

Participants appreciate hyper-personalization but seek equity, transparency, and human connection. These results underscore the need for interdisciplinary collaboration to ensure that digital health systems are technologically advanced, ethically sound, and socially inclusive.

Repositioning the Patient: Conceptual and Thematic Foundations of the PAO Model

This analysis reframed the PAO model by combining insights from biomedical innovation and marketing theory, viewing patients as active, data-driven participants in digital health systems. Traditionally, patient engagement focused on clinical outcomes or behavior change. The PAO model expands on this by positioning patients as strategic actors supported by tools such as wearables, mHealth apps, AI, and predictive analytics.

The scoping review identified 8 recurring themes where marketing concepts such as STP, CRM, behavioral economics, and co-creation intersect with biomedical technologies to create adaptive, personalized care ecosystems. Patients increasingly take on organizational roles including *strategy*, using data to set health priorities; *governance*, managing consent, trust, and accountability; and *operations*, coordinating daily care with digital tools.

Marketing analogies help clarify this shift. AI segmentation mirrors retail targeting but is used here for real-time health decisions. CRM becomes a patient-care platform, while nudging and digital branding influence health behaviors, much like tech firms shape user choices.

Although these analogies make the PAO model relatable, they rely heavily on conceptual models and pilot studies, lacking the clinical rigor expected in health care. The model's strength lies in making new patient roles visible; its weakness lies in limited empirical support.

Ultimately, the PAO model moves beyond metaphor, presenting patients as informed, autonomous agents in digitally enabled care. However, real-world challenges, like power imbalances, access barriers, and ethical risks, remain. For the model to mature, it must blend the creativity of marketing insights with the credibility of clinical and behavioral evidence.

Key Research Gaps in the PAO Model and Marketing-Driven Digital Health With Biomedical Integration

Limited Empirical Validation of the PAO Model

Although the PAO model offers strong conceptual foundations, there is a notable lack of empirical studies demonstrating how patients engage in organizational-like behaviors using digital health technologies. The existing literature tends to focus on potential rather than observed behaviors [36]. To substantiate the PAO framework, there is an urgent need for longitudinal, ethnographic, and practice-based research that captures patient engagement across diverse cultural and clinical contexts.

Inconsistent Application of Marketing Theories in Health Care

Despite the established value of marketing frameworks such as STP, CRM, and behavioral marketing in other industries, their integration in health care remains fragmented. The literature review revealed a lack of standardization in the application of these theories to influence patient engagement or health outcomes. There is a research gap in developing an evidence-based framework that operationalizes these theories via biomedical technologies and ties them to measurable behavioral or clinical outcomes [37].

Underexplored Intersection of Health Equity and Digital Access

The review highlighted persistent health disparities rooted in socioeconomic status, geography, and digital literacy [38]. Although these structural barriers are well-documented individually, few studies explore how they intersect with the PAO framework or shape patient access to digital health tools. Future research should prioritize equity-focused design and examine how inclusive strategies can effectively close the digital divide in practice, rather than just in theory.

Neglected Ethical and Regulatory Dimensions of Digital Health Marketing

Ethical concerns, such as informed consent, data transparency, algorithmic bias, and digital nudging, are acknowledged across multiple sources [39]. However, in-depth theoretical engagement remains sparse. Most studies briefly address these issues without providing analytical frameworks or policy recommendations. This gap underscores the need for comprehensive ethical models that can guide the development and deployment of AI-driven marketing in health care settings.

Insufficient Understanding of AI's Impact on Trust and Autonomy

Although AI offers significant potential for care personalization, the implications for patient trust, autonomy, and long-term relationships with health care providers are poorly understood [40]. The review revealed a lack of studies examining how predictive analytics influence user experience, clinical decision-making, or interpersonal dynamics in digital care environments. Responsible AI implementation requires empirical research that evaluates these relational dimensions.

Lack of Empirical Work on Nudging and Behavioral Economics

Behavioral economics and digital nudging are frequently cited as promising tools for influencing health behaviors [41]. However, the literature offers few empirical studies on their effectiveness in complex or high-stakes medical decisions. Experimental designs and real-world field studies are necessary to investigate how interface design, default options, and incentive framing influence behavior, particularly when ethical boundaries are being tested.

The Need for an Integrated, Evidence-Based Framework

Perhaps the most critical gap identified was the lack of a comprehensive PAO framework that cohesively combines marketing theory, behavioral psychology, and biomedical

innovation. Current research is scattered across disciplinary silos and lacks a unified theory that can capture the complexity of digitally enabled, ethically nuanced patient engagement [42]. Filling these gaps requires a cross-disciplinary approach that is both essential and collaborative. Researchers must go beyond conceptual enthusiasm and move toward empirical validation, creating inclusive, ethically sound systems that empower patients without compromising trust or equity [43]. Only then can the PAO model develop into a practical, evidence-based foundation for personalized and participatory digital health care.

This study revealed a powerful shift underway in health care: Patients are no longer just following care plans; they're actively shaping them. With the support of digital tools like wearables, mobile apps, and AI-driven platforms, many are setting health goals, tracking their progress, and making informed decisions. These behaviors closely resemble how organizations operate [44].

The scoping review showed that technologies are increasingly infused with marketing strategies like personalization, segmentation, CRM, and digital nudging. In interviews, these concepts came to life. Patients were not just using apps to manage symptoms; they were navigating complex decisions, often independently, guided by digital feedback.

However, this transformation isn't universal. Although some patients found empowerment, others faced barriers, limited digital access, low tech literacy, or distrust in AI. Alongside enthusiasm, participants expressed concerns about losing human touch, data misuse, or feeling subtly manipulated by digital nudges [45].

These tensions reveal a deeper truth: The future of health care isn't just about technology; it's about how that technology is designed, delivered, and experienced. Patients want digital tools that support, not replace, human care. Many envisioned a *blended model*—one where empathy and innovation go hand in hand [46].

Ultimately, the PAO model is no longer just a metaphor. It's emerging in real life but unevenly. To realize its full potential, future systems must be co-created with patients, grounded in trust, and built for equity not just efficiency.

This research shows that a quiet transformation is happening in medicine. Patients are no longer just recipients; they are now active participants in managing their health experiences. Through technologies such as wearables, apps, and AI platforms, patients are taking control and making real-time decisions tailored to their needs [47]. As a result, these patients are assuming responsibilities that are increasingly like self-management and self-organization.

However, this shift involves more than just technology. It also depends on how people feel, how they trust, whether they think they can maintain control, and whether they believe the systems support them. Although some tools, such as digital nudging and CRM reminders, help patients stay on track, others can make them feel anxious. Concerns about data privacy, algorithmic data misuse, and the loss of the human touch are common.

What is clear is that this transformation has great potential if approached thoughtfully. Empowerment must be balanced with protection. For the PAO model to guide future care, it needs to reflect what technology can do and what people want to achieve.

Comparison With Prior Work

Prior work in digital health has practically proven escalating patient engagement with the assistance of vehicles such as wearables, mHealth apps, and AI-driven platforms. Ahadzadeh et al [24], for example, examined how the integration between the health belief model and the technology acceptance model dictated patient behavior in digital environments. In contrast, Rongkavilit et al [30] applied the IMB model to study medication behavior in teenagers infected with HIV/AIDS. These indicate the potential of digital tools to enhance motivation, information access, and behavioral skills [30]. These, however, primarily depict patients' empowerment resulting from educational exposure or risk awareness, with little attention to patients as agency-rich actors with the potential for system-level agency.

Reframing Empowerment Within the PAO Model

In addition, this research contributes to the expanding body of digital health literature, as it recasts this concept of empowerment through the PAO framework. This indicates that, as part of this paradigm, patients are not just receiving and using digital health technology but are strategic and savvy about their own data, as would be expected of organizations, not humans.

Both personalization and nudging have been touted as means of improving engagement, yet, as we explored through interviews, a more nuanced picture is emerging. Concerns about lack of transparency and accountability, as well as manipulation, have been voiced by patients, emphasizing that patient empowerment is more than mere behavior—it is ethical as well [48].

Key Contributions

Adding Patient Organizational and Strategic Roles as an Expansion of the Idea of Empowerment

Behavior model integration (eg, HBM, IMB, or CRM) into a multilevel, ethics-focused PAO framework addresses structural inequality and moral controversies, especially for marginalized user communities, by providing practical validation through patient experiences that reveal both the potential and the vulnerabilities of technology.

Structural Inequities

There is inequality in access to digital care. Some participants, especially those lacking sufficient digital literacy and computer access, experienced identifiable barriers described under the "structural barriers" code (Table 5), which is encapsulated under inequities in digital empowerment (Table 6). Such barriers, as identified in Figure 3, lie at the intersections of trust, accessibility, and ability, emphasizing that care systems should be built for all and not just for digital sophisticates.

Trust, Ethics, and Digital Engagement

By contrast, trust was a motivator and an inhibitor of engagement. Doubts and reservations about data usage or about

algorithms and nudging, coded under trust and ethical friction (Table 5), often revolve around ethical issues that have been aggregated into the theme of negotiating trust and ethical transparency (Table 6), emphasizing that, although medical systems need to be efficient, they should be transparent and eminently explainable and that patient autonomy must be respected.

Finding Meaning and Connection

Despite this momentum in confidence in digital technology, one key takeaway was evident—the need for emotional connection remained. Apps and AI technology might be incredibly convenient and informative, but in no way could these technologies provide emotional understanding, particularly with emotional experiences and more complex medical choices. The best possible solution continued to be that found within the process of blended care (see "blended care as the preferred future" in Figure 3), where digital technology interacted with emotional connection and interpersonal trust that was found to be absolutely critical to the process of care in the digital age.

Strengths and Weaknesses

A key strength of this study was its mixed methods approach, which combines a broad literature review with rich qualitative insights. The use of grounded theory enabled the emergence of nuanced, real-world themes that reflect the diversity of patient experiences.

However, the study was limited by a relatively small and context-specific sample in the qualitative phase. Broader validation across diverse populations and health care systems will be needed to assess generalizability. Additionally, the scoping review was conceptual in nature and did not include a formal risk-of-bias assessment.

Contributions to Theory and Practice

This study makes several contributions to the evolving digital health literature. It *redefines patient empowerment* as a multilevel, ethically grounded process that includes digital skills, trust-building, and system-level support. It integrates *behavioral models* (eg, health belief model, CRM) with real-time technologies to understand how patients engage with care dynamically. It adds patient perspectives on *equity, ethics, and lived experience*, which are often missing from technologically focused research. It validates the PAO model through empirical data, showing how patients actively manage care but also struggle with ethical ambiguity and structural barriers.

Future Directions

Future studies should consider equity-oriented design and co-creation as well as research into trust, behavior, and adoption over time or other studies on ethical metrics for nudging, personalization, and AI adoption and use in patient care and outcomes today. It is imperative that, in the future, a PAO model be one of innovation, grounded in patients' experiences, anxieties, and values.

To ensure that the PAO model becomes an empirical reality and shifts from theoretical to practical application, the following should be prioritized in subsequent research: (1) equity-informed design: design technologies to be accessible to everyone; (2) co-creation with patients: engage patients in the design process, evaluation, and governance of digital health applications; (3) transparent and ethical infrastructures: develop consent dashboards and explainable AI; and (4) longitudinal study research: study digital behavior trust processes over time.

Conclusion

This paper examined another important change that has come about in the health care sector. Patients are no longer passive receivers of health care but are actively participating in it with the use of technology such as wearables, health apps, and AI platforms. Technology is giving people the capacity to take charge of their health care choices [49].

We conducted our study through the review of existing literature and in-depth interviews to explore how the application of marketing approaches, such as personalization, nudging, and CRM, is integrated with digital health platforms. The PAO conceptual framework provides valuable insights to understand this transformation and recognizes that patients are "consumers" no more but act like strategic actors who use data to manage health just like any other organizational entity.

What our research tells us is that, for some patients, particularly those with robust digital connectivity and savvy, this scenario has already begun to come to fruition. Many of the patients surveyed consider themselves to be planners or "health managers," utilizing digital feed-forward and tracking applications to shape decisions. However, such technologies are certainly not ubiquitous. Members from underserved groups presented authentic challenges to digital health adoption, such as connectivity difficulties and unfamiliarity with AI applications.

Additionally, there are other ethical considerations that must be considered. Although data personalization and nudging can be beneficial to patient health outcomes, there are worries about transparency or manipulation and autonomy if patients do not fully understand algorithmic influences [50].

Despite these challenges, the PAO model provides significant insight into what is happening to the role of the patient. Rather than viewing it as something that is complete and finished—something that needs to be applied—the best way to look at it is to realize that it can be seen as more of a thought process about the future of health care that must allow for adjustment and change.

In the end, this model encourages us to reconsider the role of patients—be it within health care as recipients of care but also as active contributors to the creation thereof. With such caution and care taken in its development, the PAO approach might lead to a more participatory and trustable future in health. Only then can we ensure that digital health is not just innovative but also inclusive, trustworthy, and deeply human.

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Data Availability

The datasets generated during and/or analyzed during this study are available from the corresponding author upon reasonable request.

Authors' Contributions

Conceptualization: ADG
Data curation: YY
Formal analysis: ADG
Investigation: YY
Methodology: ADG
Validation: YY
Visualization: ADG
Writing – original draft: ADG
Writing – review & editing: YY

Conflicts of Interest

None declared.

Checklist 1
PRISMA-ScR checklist.
[DOCX File, 18 KB - biomedeng_v11i1e77115_app1.docx]

Checklist 2
COREQ checklist.
[DOCX File, 16 KB - biomedeng_v11i1e77115_app2.docx]

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Abbreviations

AI: artificial intelligence
CRM: customer relationship management
IMB: information-motivation-behavioral skills
mHealth: mobile health
PAO: patient as an organization
PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews
RQ: research question
STP: segmentation, targeting, and positioning
WHO: World Health Organization

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Increasing Large Language Model Accuracy for Care-Seeking Advice Using Prompts Reflecting Human Reasoning Strategies in the Real World: Validation Study

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Abstract

Background: Current prompting techniques for large language models (LLMs), such as ChatGPT, mainly focus on well-structured, low-uncertainty problems; yet, many real-world tasks (eg, care-seeking decisions) are ill-defined and involve high uncertainty. Naturalistic decision-making (NDM) specifically analyzes how humans make accurate decisions in such settings, but NDM concepts have not yet been applied to LLM prompt engineering.

Objective: This study aimed to determine whether prompting strategies inspired by NDM (specifically based on recognition-primed decision-making and the data-frame theory) could improve LLM performance in a real-world, high-uncertainty task, such as making care-seeking decisions.

Methods: We evaluated 10 ChatGPT models (GPT-4o, GPT-4.1, GPT-4.1 mini, o3, o4 mini, o4 mini high, GPT-5.1 Instant, GPT-5.1 Thinking, GPT-5.2 Instant, and GPT-5.2 Thinking) using 3 prompting strategies: a default prompt solely asking the LLMs to classify the case vignettes, a recognition-primed prompt tasking the models to reason according to recognition-primed decision-making, and a data-frame prompt tasking the models to apply the data-frame theory. The task was taken from a standardized and validated evaluation framework and instructed the LLMs to advise on the appropriate care-seeking action for 45 real patient case vignettes across 3 urgency levels (emergency, nonemergency, and self-care). Each model-vignette-prompt combination was tested 10 times to assess and account for output variability. Accuracy was analyzed using mixed effects logistic regression. Additionally, we evaluated accuracy for each urgency level and examined output variability.

Results: Both NDM-inspired prompts increased overall model accuracy (recognition-primed: 67.6%; data-frame: 66.7%) compared to the default prompt (63.3%). The greatest improvements were observed for self-care recommendations, where accuracy increased from 13.4% (default prompt) to 29.8% (recognition-primed prompt) and 24.6% (data-frame prompt). Performance on 2 emergency and 30 nonemergency cases remained high across all prompts. Notably, NDM-inspired prompts made nonreasoning models start giving self-care advice, even though they rarely or never provided self-care advice with the default prompt. Output variability was similar across the 3 prompts.

Conclusions: Using LLMs with prompts inspired by NDM, which are designed to reflect real-world human reasoning, improves the accuracy of LLMs in care-seeking tasks, particularly for self-care advice, without reducing performance in the included emergency or nonemergency cases. These findings indicate that NDM-inspired prompts can offer an advantage when LLMs are used for real-world decisions involving ambiguity and uncertainty. The impact of output that reflects real-world human reasoning on users' decision-making must be evaluated in future studies.

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KEYWORDS

prompting; human-technology interaction; human factors; artificial intelligence; decision-making; naturalistic decision-making; naturalistic decision support; cognitive science; care-seeking; self-triage; bounded rationality

Introduction

Since their public release in 2022, large language models (LLMs), such as ChatGPT, have become widely used across domains for a range of tasks [1-8]. Although these models now reach high levels of accuracy on several benchmark tests, both researchers and users are increasingly interested in techniques to further improve model performance through specific input instructions—a process known as "prompting" [9]. Common approaches include assigning the model a specific role,

providing relevant context or examples, or specifying a clear output format [10-12]. Three basic prompting strategies are often described in the literature: zero-shot, one-shot, and few-shot prompting. Zero-shot prompting refers to providing only the task instructions without any example outputs. One-shot prompting includes a single example of the expected output, and few-shot prompting provides multiple examples of the expected output [12]. In recent work, prompting strategies focus more on guiding the model through a reasoning process rather than simply providing information. A recent systematic review identified 58 prompting techniques, which were grouped into 6 categories [13]. In addition to zero-shot and few-shot approaches, 4 new categories were described: *ensembling prompts* use multiple prompts and aggregate the resulting outputs [13-16]. *Self-criticism prompts* instruct the model to evaluate and critique its own answers before responding [13,17,18]. *Decomposition prompts* instruct LLMs to break down tasks into smaller steps, which are then solved sequentially [13,19,20]. Finally, *thought generation* or "*chain-of-thought*" prompts ask the model to explicitly explain its reasoning as it works through a problem [13,21,22]. Notably, chain-of-thought and reasoning prompts have now been directly integrated into newer models [23]. For example, OpenAI's o-series models (including o1, o3, and o4) are designed to generate a reasoning response before generating a user response [23]. This approach has been shown to improve accuracy across several benchmarks [21,24,25]. Starting with GPT-5, OpenAI also introduced a new, automatically included reasoning engine that consists of several internal expert models to which a user's request is routed [26,27]. The model also automatically determines the reasoning effort needed to answer the user's request [26,27].

Although the chain-of-thought prompting strategy is inspired by human reasoning, particularly deductive decision-making, there is an ongoing debate about whether LLMs really replicate human reasoning or simply generate plausible-sounding explanations [28]. Shojaee et al [29] recently tested chain-of-thought reasoning models on increasingly complex puzzles and found that LLMs do not engage in consistent reasoning across similar problems. In response, Lawsen [30] argues that these findings can be attributed to experimental artifacts and that LLMs are indeed capable of reasoning consistently and accurately when experimental setups are properly designed. Regardless of whether LLMs truly mimic human deductive reasoning when prompted with reasoning techniques, using human decision-making as a source of inspiration for developing prompting strategies is a promising direction. This is especially true in situations with high uncertainty, where deductive reasoning quickly reaches its limits, but humans are nonetheless able to make fairly good decisions [31].

Insights from the fields of applied psychology and human factors and ergonomics (HF/E) suggest that there is a gap between how humans reason in real-world situations and the assumed standard reasoning approaches related to deduction and induction, which are typically used to instruct and evaluate LLMs [28]. One explanation for this difference may be that humans often make decisions under uncertainty, with incomplete or ambiguous information, and decision tasks and goals are often ill-structured [32-34]. In contrast, most psychology experiments, as well as the current benchmarks for LLMs, rely on well-structured, multiple-choice tasks where all necessary information is explicitly provided, and the LLMs are merely asked to choose the correct answer out of multiple options, which can be readily evaluated against a clear-cut gold standard solution [35-39]. This test format is also used in most educational assessments, and LLMs perform well on this format—for example, passing professional and board certification exams in medicine, psychotherapy, and law. As a result, LLMs are widely promoted as accurate decision-support tools for well-structured tasks, and many users use them for this purpose [37,40-45]. However, when existing models are evaluated on real-world datasets, which more accurately reflect the complexity and ambiguity in real decision-making, their performance seems to be considerably worse [2,35,46].

The distinction between decision-making in idealized situations and in complex, ill-defined real-world settings has long been recognized in behavioral economics and psychology. In 1955, Herbert Simon introduced the concept of bounded rationality to study how human decision-making takes place under limited cognitive and environmental resources rather than under the conditions of perfect knowledge and unlimited resources, the normative ideal of full rationality, which is currently assumed in many LLM benchmarks [47,48]. Building on the idea of bounded rationality, the field of naturalistic decision-making (NDM) developed to study how experts make good decisions in real-world contexts [34,49]. Research in NDM shows that, rather than exhaustively comparing all possible options, both experts and novices typically rely on a limited set of information to recognize the most promising option or action [34,50,51]. This strategy is not perfectly accurate in all situations, but it often results in highly accurate decisions within short timeframes [50,52,53]. Specifically, findings from the NDM field suggest that in situations with high information validity, experts often perform on par with complex algorithms, even when using less information and simpler strategies [31,54,55]. This can be explained by the fact that experts rarely follow a strictly deductive or inductive process. Instead, they quickly recognize which information is relevant and engage in *abductive reasoning*; that is, they generate an initial hypothesis based on the observed piece of relevant information and then seek out information to test this hypothesis and update it as new contradicting information becomes available [28,56].

To describe human decision-making in real-world scenarios, 2 models feature most prominently in the NDM literature: recognition-primed decision-making (RPD) [56] and the data-frame theory [57]. The RPD model, which is used to make quick decisions in familiar situations, consists of 2 core processes: a pattern-matching loop and a mental simulation loop [56]. In the pattern matching loop, decision-makers assess whether a situation is familiar (eg, they recognize whether they have experienced a similar situation before). If the situation is recognized as familiar, they directly implement an action. If it is unfamiliar, they either reassess the situation or seek additional information until they achieve some sense of familiarity and can proceed to the mental simulation loop. In the subsequent mental simulation loop, decision-makers simulate implementing

their chosen course of action. If they conclude that this action will most likely work, they implement it; if not, they modify the plan and reassess, or they consider new actions entirely [56].

The data-frame theory focuses more on sense-making and understanding new, unknown situations rather than on making decisions [57]. According to this model, humans use frames (basic ideas, hypotheses, or mental models about what is happening in a given context) and data (information in the environment). These 2 concepts interact: frames determine what information is noticed, sought, and how it is interpreted. At the same time, new data can lead a person to elaborate, revise, or even abandon their current frame. For example, in medical diagnosis, a physician may form an initial hypothesis (frame) based on presenting symptoms, then gather additional data to either confirm or reconsider that frame based on new information [57].

Although there is strong evidence supporting the occurrence, efficiency, and effectiveness of NDM models, such as the RPD model or the data-frame theory in real-world decision-making, these approaches have not yet been applied to instruct LLMs [58,59]. Existing reasoning prompts and models are inspired by an ideal form of human decision-making and deductive reasoning, and they seem to perform well on well-structured problems with known risks and gold-standard solutions, and less so in situations involving real-world ambiguity and uncertainty. Although for the latter situation, NDM-based strategies may prove more effective, they have not yet been applied to improve and evaluate LLM performance in ill-defined, real-world tasks. In this study, we aimed to test whether prompts based on NDM principles can improve LLM performance on a real-world, ill-defined task.

Building on our previous work, we used a standardized and validated evaluation framework that used a care-seeking or "self-triage" decision scenario involving real patient cases to evaluate NDM-based prompts [60]. Self-triage refers to the decision-making process by which people determine whether medical care is needed and, if so, where and how urgently to seek it (eg, self-care, primary care, or emergency care) [6,61,62]. This is a common decision task in everyday life, with 80% to 90% of the population reporting at least 1 symptom within a given month [63,64], and laypeople are increasingly consulting digital tools, such as LLMs, for advice [65,66]. Previous research shows that human performance in self-triage decisions is moderate and that LLMs perform only slightly better on average, although they almost always recommend professional care rather than self-care [6,67-69]. Self-triage is thus a suitable use case for the present study because it is typically ill-structured: information about symptoms may be incomplete and ambiguous, and decision-makers must decide under uncertainty. Therefore, self-triage is a representative example of the real-world decisions studied in NDM research.

We hypothesized that prompts inspired by the RPD model and the data-frame theory will significantly increase accuracy on these tasks in selecting the best course of action across both nonreasoning and reasoning models, compared to a standard zero-shot prompt.

Methods

Study Design

This evaluation study was designed as a prospective, longitudinal, observational LLM validation study. The intervention was the specific prompting strategy: a regular prompt, a recognition-primed prompt, and a data-frame prompt. We used these 3 prompting strategies to assess 45 vignettes across 10 models, each tested 10 times. The primary outcome was the accuracy of the models under each prompting condition, and the secondary outcome was the output variability of the tested models. No participants were involved in this study.

Ethical Considerations

This study did not involve any prospective recruitment, interaction, or intervention with human participants. The LLM evaluation used an existing dataset of symptom descriptions originally collected on an online platform. Ethical approval for this collection, use, and deidentification of the cases was obtained from the ethics committee of the Department of Psychology and Ergonomics at Technische Universität Berlin (AWB_KOP_2_230711). For the present study, we accessed only the deidentified version of these cases [70]. Pseudonymized identifiers (eg, user names) were completely removed, and potential quasi-identifiers in free text (eg, city or institution names) were deleted. The dataset was stored on an access-restricted institutional computer, and the data were used solely for model evaluation. No attempts were made to reidentify individuals. Accordingly, no additional ethical approval was required for this secondary analysis. The reporting of this manuscript follows the TRIPOD (Transparent Reporting of a Multivariable Model for Individual Prognosis or Diagnosis)–LLM guideline [71].

Tested Models

Because ChatGPT remains the most widely used LLM family [72], we focused our evaluation on LLMs currently available within ChatGPT. For the initial data collection, this included GPT-4o, GPT-4.1, GPT-4.1 mini, o3, o4 mini, and o4 mini high. For a second round of data collection, this included GPT-5.1 and GPT-5.2, including both the Instant and Thinking versions. All models are based on the Transformer architecture; however, o3, o4 mini, o4 mini high, GPT-5.1 Thinking, and GPT-5.2 Thinking include a reasoning process prior to generating output for users [23]. All models were tested using the default parameters to approximate consumer-facing ChatGPT model behavior. Thus, we used each model's default temperature (1), a top-p of 1, did not specify a maximum output length (max_tokens unset), and did not specify a random seed. Because outputs are stochastic without a seed, we repeated each vignette-model-prompt condition 10 times and reported variability to approximate consumer-facing behavior. For GPT-5.1 and GPT-5.2, we set the reasoning.effort parameter to none (to disable reasoning and emulate consumer-facing GPT-5.1 and GPT-5.2 Instant), and to medium (to emulate GPT-5.1 and GPT-5.2 Thinking). Additionally, we conducted a sensitivity analysis using the 2 models for which the prompts yielded the largest accuracy gains. We tested a temperature of 0 (maximum determinism/control) and did not include a higher

temperature option because the models frequently refused to provide recommendations with a temperature higher than the default temperature.

Task and Evaluation Dataset

Our task consisted of obtaining advice on which care-seeking option is most appropriate for the described symptoms. This type of task is commonly used to evaluate both digital health applications and LLMs [6,61,62,73-75]. We selected it specifically because it reflects a real use case for ChatGPT [68,76-80], involves uncertainty (ie, unknown risks), and often deals with ambiguous or incomplete data or symptoms. For these reasons, we considered this task well suited to test the influence of NDM-inspired prompts on LLM performance in real-world problems.

The dataset was developed in previous studies and followed current guidelines for evaluating care-seeking decision support systems [70,81-83]. From an "ask the doctor" online platform, 45 real patient cases, where medical laypeople described their symptoms and sought advice from professionals, were collected between October 2023 and January 2024 and psychometrically validated [70,81]. Cases were further stratified to reflect the natural base rates of symptom types that are typically entered into online care-seeking advice tools based on the Centers for Disease Control and Prevention's National Ambulatory Medical Care Survey [70,84]. Because of this stratification, the dataset included only 2 emergency care cases, 30 nonemergency care cases, and 13 self-care cases. To minimize editing effects, only typos were corrected. The original cases cannot be reproduced in this manuscript for copyright reasons, but they are available from the authors upon reasonable request. The cases describe acute symptoms for which laypeople seek decision support on whether and where to seek care. They cover a range of physical symptom presentations across specialties and are written in natural, nontechnical language from the perspective of medical laypeople. For example, 1 case describes a person reporting pain near the chest or lung area during the night when lying down, which improves when upright but worsens with breathing. After a few minutes, the person noticed a weird sensation, and the pain went away. The person then asks whether they should still seek medical care. Another exemplary case describes a person who notices a visible dent in the lower leg or heel area after sitting with one leg crossed for about 20 minutes. The person says this happens often and is usually painless, but this time the legs seem more swollen than usual, so the dent lasts longer.

To determine the most appropriate level of care, a physician panel consisting of 2 licensed physicians independently rated each case and then discussed their assessments until they reached a consensus assignment on 3 possible care-seeking options: (1) emergency care, defined as situations requiring emergency department visits; (2) nonemergency care, where consulting a general practitioner or another medical specialist is appropriate; and (3) self-care, where patients can monitor or manage symptoms themselves. Further details on the dataset are available in our publication on the RepVig framework [70].

Since the prompts included a specific output format, we used text pattern–based matching to extract the recommendation given by the LLM. If no direct match was found, we assessed the cases manually.

Prompts

To evaluate the baseline accuracy of the tested models, we used the prompt shown in Textbox 1. This prompt was developed in previous studies evaluating the care-seeking advice of LLMs [67,69,70,85] and was adapted to specify an output structure (ie, "Answer: Classification") that enabled us to classify model responses using natural language processing.

The NDM-inspired prompts were based on this base prompt but additionally included the name of the respective model (ie, "Recognition-Primed Decision-Making model" and "Data-Frame-Theory approach") to prime the LLMs accordingly. Each prompt then provided instructions on how to reason following the principles of the corresponding model. The full prompts are shown in Textbox 2.

Textbox 1. Care-seeking advice prompt used in the control group to determine the base accuracy of the tested large language models.

Please give a triage classification for the following vignette. The criteria for triage classifications are presented below:

- Emergency: Call 911 or go directly to the emergency room;
- Nonemergency: Try to see a doctor, but the symptoms do not require immediate attention at an emergency room. For example, you can see a doctor in the next week.
- Self-care: Let the health issue get better on its own and review the situation again in a few days.

Respond in the following format:Answer: Your answer [either Emergency, Nonemergency, or Self-Care].

Textbox 2. Recognition-primed prompt instructing the large language models to reason according to the recognition-primed decision-making model.

Please give a triage classification for the following vignette. The criteria for triage classifications are presented below:

- Emergency: Call 911 or go directly to the emergency room;
- Nonemergency: Try to see a doctor, but the symptoms do not require immediate attention at an emergency room. For example, you can see a doctor in the next week.
- Self-care: Let the health issue get better on its own and review the situation again in a few days.

Use the recognition-primed decision-making model to make your decision. Does this situation match any typical cases you know? If yes, what is the usual decision for such a case? Simulate implementing this decision for the described situation and test whether it will work. If not, modify it and test again whether it will work. If the situation is not similar to any typical case you know, try to reassess the situation until you think it sounds familiar, simulate the implementation again, and test whether it will work.

Respond in the following format:Analysis: Your analysis || Answer: Your answer [either Emergency, Nonemergency, or Self-Care].

Textbox 3. Data-frame prompt instructing the large language models to reason according to the data-frame theory.

Please give a triage classification for the following vignette. The criteria for triage classifications are presented below:

- Emergency: Call 911 or go directly to the emergency room;
- Nonemergency: Try to see a doctor, but the symptoms do not require immediate attention at an emergency room. For example, you can see a doctor in the next week.
- Self-care: Let the health issue get better on its own and review the situation again in a few days.

Before giving your triage classification, think about the correct classification using the Data-Frame-Theory approach. As you analyze the vignette, actively use the following reasoning processes (as needed, not necessarily in order):

- Construct or recognize a frame: Identify the main interpretation or mental model that organizes the case information.
- Elaborate the frame: Seek out or infer additional relevant details from the vignette.
- Question the frame: Look for inconsistencies, surprising data, or violated expectations.
- Preserve the frame: Consider whether your interpretation still fits, or if any data needs to be reinterpreted.
- Seek a new frame: If appropriate, consider alternative interpretations.
- Reframe: Revise your perspective and reinterpret the data if needed.
- Compare frames: Identify and weigh alternative ways of understanding the case.

Respond in the following format:Reflection process: Your reflection || Answer: Your answer [either Emergency, Nonemergency, or Self-Care].

All prompts were tested for feasibility in a pretest, during which the authors tested the prompts and API calls using random cases and manually assessed the output for adherence to the instructions and correct formatting.

Procedure

We used a custom-built Python script to access the OpenAI API on May 23, 2025, and a second time for newer models on February 23, 2026. For each model, the prompts (Textboxes 1-3) were entered as system prompts, and the case vignettes as user prompts. The context window was cleared before every call. Because of the high output variability observed in LLMs [67,86,87], we tested each model on each case 10 times as a quality-management measure to account for the fact that different users may receive different advice for the same input. Model outputs were then classified automatically in R into 3 categories (emergency, nonemergency, self-care). For cases in which the category could not be determined through keyword or pattern matching (n=61), manual coding was performed by reading through the answer and assigning a classification manually.

Outcome Measures

The primary outcome was classification accuracy, defined as whether the model's triage recommendation matched the physician-panel gold standard reference for each vignette (ie, correct or incorrect). This metric was chosen because it most closely measures the potential behavioral and safety impact the prompts can have on users. Secondary outcomes included the accuracy by each triage level (emergency, nonemergency, or self-care), calculated as the proportion of correct recommendations within each stratum. Additionally, because the vignette set included only 2 emergency cases, we dichotomized the triage levels into 2 groups: requiring medical care versus self-care. Next, we assessed output variability using Fleiss' Kappa for each model-vignette-prompt combination, and by assessing the consistency of model recommendations, that is, the proportion of the 10 trials corresponding to the most frequently given recommendation. Lastly, we assessed technical accuracy by coding whether the correct recommendation was given at least once among all 10 trials.

Data Analysis

All analyses were conducted in R using the packages symptomcheckR, tidyverse, psych, and lme4 [88-91]. To assess the accuracy of each prompt, we calculated the mean proportion of correctly solved cases and quantified precision using 95% CIs. To test our hypothesis that the NDM-inspired prompts increase LLM performance, we used mixed effects binomial logistic regression (with prompt type as a fixed effect and random intercepts for model, vignette, and model-by-vignette combination to account for repeated observations and clustering in our data—that is, for having each model assess each vignette 10 times) with 2-sided tests. Additionally, we conducted subgroup analyses to assess accuracy in dichotomized decisions (ie, professional care vs self-care), accuracy by model, and accuracy by each care-seeking level. In sensitivity analyses, we further tested whether the reported results remained stable with a low-temperature setting. We chose the 2 models with the highest and lowest prompt-dependent accuracy improvement (ie, GPT-4.1 mini and GPT-5.2 Instant).

To quantify output variability for each prompt, vignette, and model combination, we calculated Fleiss κ and recorded the frequency with which the most common recommendation was given across the 10 trials for each vignette and model. As an estimate of "technical accuracy" (ie, whether the model was technically capable of generating the correct advice), we noted whether the correct recommendation was given at least once in 10 trials [67,92].

Results

Assessments

We used 45 vignettes to test 10 models, with each model run 10 times per vignette using 3 prompting strategies (default, recognition-primed prompting, and data-frame prompting). This resulted in a total of 13,500 individual assessments.

Overall Accuracy of Each Prompt

The average accuracy across all models, vignettes, and trials was 63.3% (95% CI 61.9% - 64.7%) for the default prompt, 67.6% (95% CI 66.3% - 69%) for the recognition-primed prompt, and 66.7% (95% CI 65.3% - 68%) for the data-frame prompt. Both the recognition-primed prompt (OR 2.26, z=8.69; P<.001) and the data-frame prompt (OR 2.05, z=7.23; P<.001) significantly increased accuracy compared to the default prompt. Improvements were greater for reasoning models than for nonreasoning models (OR 2.15, z=4.05, P<.001 for the recognition-primed prompt and OR 1.70, z=2.65, P=.008 for the data-frame prompt). The largest increase in accuracy compared to the default prompt was observed for GPT-4.1 mini with the data-frame prompt, with an improvement of 13 percentage points (95% CI 9.7 - 16.1), as shown in Table 1. In a binary choice, that is, care versus self-care, results remained similar, as shown in Table S1 in Multimedia Appendix 1. The same holds true when tested with a low-temperature setting, as shown in Table S2 in Multimedia Appendix 1.

Table . The accuracy of all tested models for each prompt.

Model	Default prompt, mean (95% CI)	Recognition-primed prompt, mean (95% CI)	Data-frame prompt, mean (95% CI)	Model type
Overall (%)	63.3 (61.9 - 64.7)	67.6 (66.3 - 69)	66.7 (65.3 - 68)	—[a]
GPT-4o (%)	65.3 (60.8 - 69.6)	70.7 (66.3 - 74.7)	66.2 (61.7 - 70.4)	Nonreasoning
GPT-4.1 (%)	64.4 (59.9 - 68.7)	72.7 (68.4 - 76.6)	72.4 (68.1 - 76.4)	Nonreasoning
GPT-4.1 mini (%)	49.8 (45.2 - 54.4)	60.7 (56.1 - 65.1)	62.4 (57.9 - 66.8)	Nonreasoning
o3 (%)	70.7 (66.3 - 74.7)	75.1 (70.9 - 78.9)	76.2 (72.1 - 79.9)	Reasoning
o4 mini (%)	69.3 (64.9 - 73.4)	70.7 (66.3 - 74.7)	72.9 (68.6 - 76.8)	Reasoning
o4 mini high (%)	68.9 (64.5 - 73)	71.3 (67 - 75.3)	70.7 (66.3 - 74.7)	Reasoning
GPT-5.1 Instant (%)	64 (59.4 - 68.4)	71.1 (66.7 - 75.3)	66.2 (61.6 - 70.6)	Nonreasoning
GPT-5.1 Thinking (%)	70.7 (66.2 - 74.8)	74.7 (70.4 - 78.6)	72.4 (68.1 - 76.5)	Reasoning
GPT-5.2 Instant (%)	57.8 (53.1 - 62.4)	56.4 (51.7 - 61.1)	55.3 (50.6 - 60)	Nonreasoning
GPT-5.2 Thinking (%)	52 (47.3 - 56.7)	53.1 (48.4 - 57.8)	51.8 (47.1 - 56.5)	Reasoning

[a]Not available.

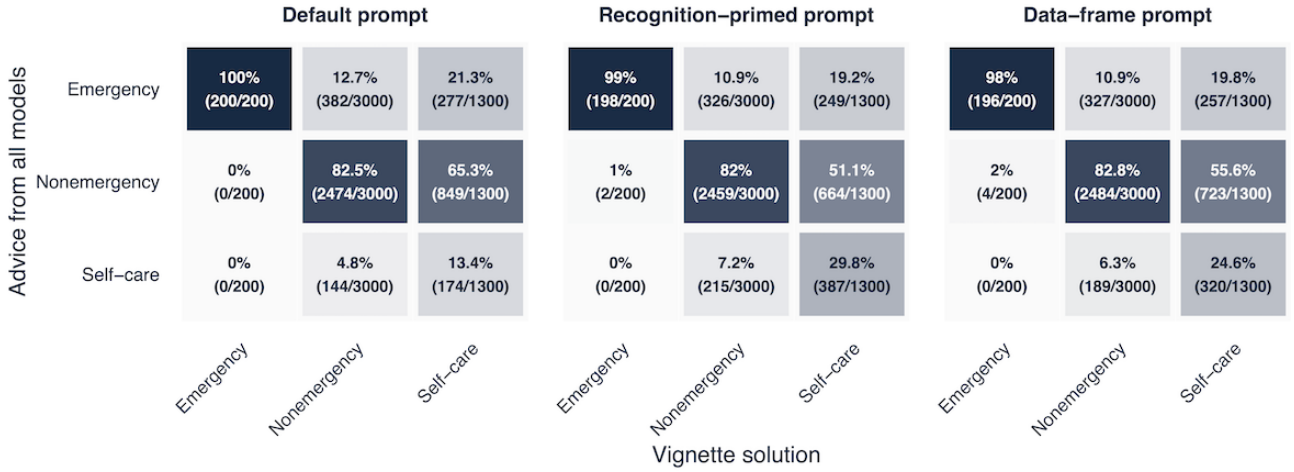
The recognition-primed prompt increased accuracy in 18 of 45 cases (40%) and decreased accuracy in 13 cases (29%) on average across all models. Its median increase in accuracy was 18% (IQR 5% - 24%), whereas the median decrease was 5% (IQR 2% - 7%). The data-frame prompt increased accuracy in 17 of 45 (38%) cases and reduced it in 12 (27%) cases. Its median increase in accuracy was 14% (IQR 4% - 19%), and the median decrease was 5% (IQR 3% - 8%). Most decreases in accuracy affected nonemergency cases (12/13, 92% for the recognition-primed prompt and 11/12, 92% for the data-frame prompt, see the Triage-Level Accuracy of Each Prompt section for the direction). Increases were observed in both nonemergency and self-care cases (8/18, 44%, and 10/18, 56%, respectively, for the recognition-primed prompt; 8/17, 47%, and 9/17, 53%, for the data-frame prompt, see the next section for the direction) (Table S3 in Multimedia Appendix 1).

Triage-Level Accuracy of Each Prompt

Across all 3 prompts, the models tended to recommend higher-than-necessary urgency (accounting for 88% of all errors,

95% CI 87% - 88.9%) rather than lower-than-necessary urgency (12% of all errors, 95% CI 11.1% - 13%). With the default prompt, both emergency cases were correctly identified (100%, 95% CI 98.2% - 100%). Using both the data-frame prompt and the recognition-primed prompt, both emergency cases were also mostly identified correctly (99%, 95% CI 96.4% - 99.9% and 98%, 95% CI 95% - 99.5%, respectively), although some trials resulted in incorrect nonemergency advice (1%, 95% CI 0.1% - 3.6% and 2%, 95% CI 0.5% - 5%, respectively). Accuracy for nonemergency cases was similar across all prompts: 82.5% (95% CI 81.1% - 83.8%) for the default prompt, 82% (95% CI 80.5% - 83.3%) for the recognition-primed prompt, and 82.8% (95% CI 81.4% - 84.1%) for the data-frame prompt. The largest difference was observed for self-care cases: With the default prompt, the models correctly identified only 13.4% (95% CI 11.6% - 15.4%), compared to 29.8% (95% CI 27.3% - 32.3%) with the recognition-primed prompt and 24.6% (95% CI 22.3% - 27.1%) with the data-frame prompt (Figure 1). The results remained similar in a binary choice task and also when tested with a low temperature setting (Tables S1 and S4 in Multimedia Appendix 1).

Figure 1. Confusion matrix showing the classification of each prompt across all models compared to the correct vignette solution. Emergency estimates may be unreliable because only 2 cases were included.



Notably, nonreasoning models that never or rarely provided self-care advice with the default prompt began providing self-care advice with relatively high accuracy when using the NDM-inspired prompts (eg, 0%, 95% CI 0% - 2.9% for the default prompt in GPT-4.1, compared to 43.8%, 95% CI 35.6% - 52.4% for the recognition-primed prompt and 39.2%, 95% CI 31.3% - 47.8% for the data-frame prompt). For reasoning models, which already gave self-care advice with the default prompt, accuracy further improved with the NDM-inspired prompts (eg, 46.9%, 95% CI 38.6% - 55.5% with the default prompt in o4 mini; 63.8%, 95% CI 55.3% - 71.6% with the recognition-primed prompt; and 56.2%, 95% CI 47.6% - 64.4% with the data-frame prompt; Table 2).

Table . Accuracy of each model and prompt in generating care-seeking advice by correct vignette solution.

Model and vignette type	Default prompt, mean (95% CI)	Recognition-primed prompt, mean (95% CI)	Data-frame prompt, mean (95% CI)
GPT-4o (%)			
Emergency (n=2)	100 (83.9 - 100)	100 (83.9 - 100)	100 (83.9 - 100)
Nonemergency	90.3 (86.5 - 93.2)	92.3 (88.8 - 94.8)	87.7 (83.5 - 90.9)
Self-care	2.3 (0.8 - 6.6)	16.2 (10.8 - 23.4)	11.5 (7.1 - 18.2)
GPT-4.1 (%)			
Emergency (n=2)	100 (83.9 - 100)	100 (83.9 - 100)	80 (58.4 - 91.9)
Nonemergency	90 (86.1 - 92.9)	83.3 (78.7 - 87.1)	86.3 (82 - 89.8)
Self-care	0 (0 - 2.9)	43.8 (35.6 - 52.4)	39.2 (31.3 - 47.8)
GPT-4.1 mini (%)			
Emergency (n=2)	100 (83.9 - 100)	100 (83.9 - 100)	100 (83.9 - 100)
Nonemergency	68 (62.5 - 73)	81.3 (76.5 - 85.3)	87 (82.7 - 90.3)
Self-Care	0 (0 - 2.9)	6.9 (3.7 - 12.6)	0 (0 - 2.9)
o3 (%)			
Emergency (n=2)	100 (83.9 - 100)	100 (83.9 - 100)	100 (83.9 - 100)
Nonemergency	93.7 (90.3 - 95.9)	90.7 (86.8 - 93.5)	92.7 (89.1 - 95.1)
Self-care	13.1 (8.3 - 19.9)	35.4 (27.7 - 43.9)	34.6 (27 - 43.1)
o4 mini (%)			
Emergency (n=2)	100 (83.9 - 100)	100 (83.9 - 100)	100 (83.9 - 100)
Nonemergency	77 (71.9 - 81.4)	71.7 (66.3 - 76.5)	78.3 (73.3 - 82.6)
Self-care	46.9 (38.6 - 55.5)	63.8 (55.3 - 71.6)	56.2 (47.6 - 64.4)
o4 mini high (%)			
Emergency (n=2)	100 (83.9 - 100)	100 (83.9 - 100)	100 (83.9 - 100)
Nonemergency	75.7 (70.5 - 80.2)	74.7 (69.5 - 79.3)	74 (68.8 - 78.6)
Self-care	48.5 (40 - 57)	59.2 (50.6 - 67.3)	58.5 (49.9 - 66.6)
GPT-5.1 Instant (%)			
Emergency (n=2)	100 (83.9 - 100)	95 (76.4 - 99.1)	100 (83.9 - 100)
Nonemergency	87 (82.7–90.3)	86 (81.6 - 89.5)	88 (83.8 - 91.2)
Self-care	5.4 (2.6 - 10.7)	33.1 (25.6 - 41.5)	10.8 (6.5 - 17.3)
GPT-5.1 Thinking (%)			
Emergency (n=2)	100 (83.9 - 100)	95 (76.4 - 99.1)	100% (83.9% - 100%)
Nonemergency	92 (88.4 - 94.6)	90 (86.1 - 92.9)	87 (82.7 - 90.3)
Self-care	16.9 (11.4 - 24.3)	36.2 (28.4 - 44.7)	34.6 (27 - 43.1)
GPT-5.2 Instant (%)			
Emergency (n=2)	100 (83.9 - 100)	100 (83.9 - 100)	100 (83.9 - 100)
Nonemergency	80 (75.1 - 84.1)	76.7 (71.6 - 81.1)	76.3 (71.2 - 80.8)
Self-care	0 (0 - 2.9)	3.1 (1.2 - 7.6)	0 (0 - 2.9)
GPT-5.2 Thinking (%)			
Emergency (n=2)	100 (83.9 - 100)	100 (83.9 - 100)	100 (83.9 - 100)
Nonemergency	71 (65.6 - 75.8)	73 (67.7 - 77.7)	70.7 (65.3 - 75.5)
Self-care	0.8 (0.1 - 4.2)	0 (0 - 2.9)	0.8 (0.1 - 4.2)

Output Variability of Each Prompting Technique

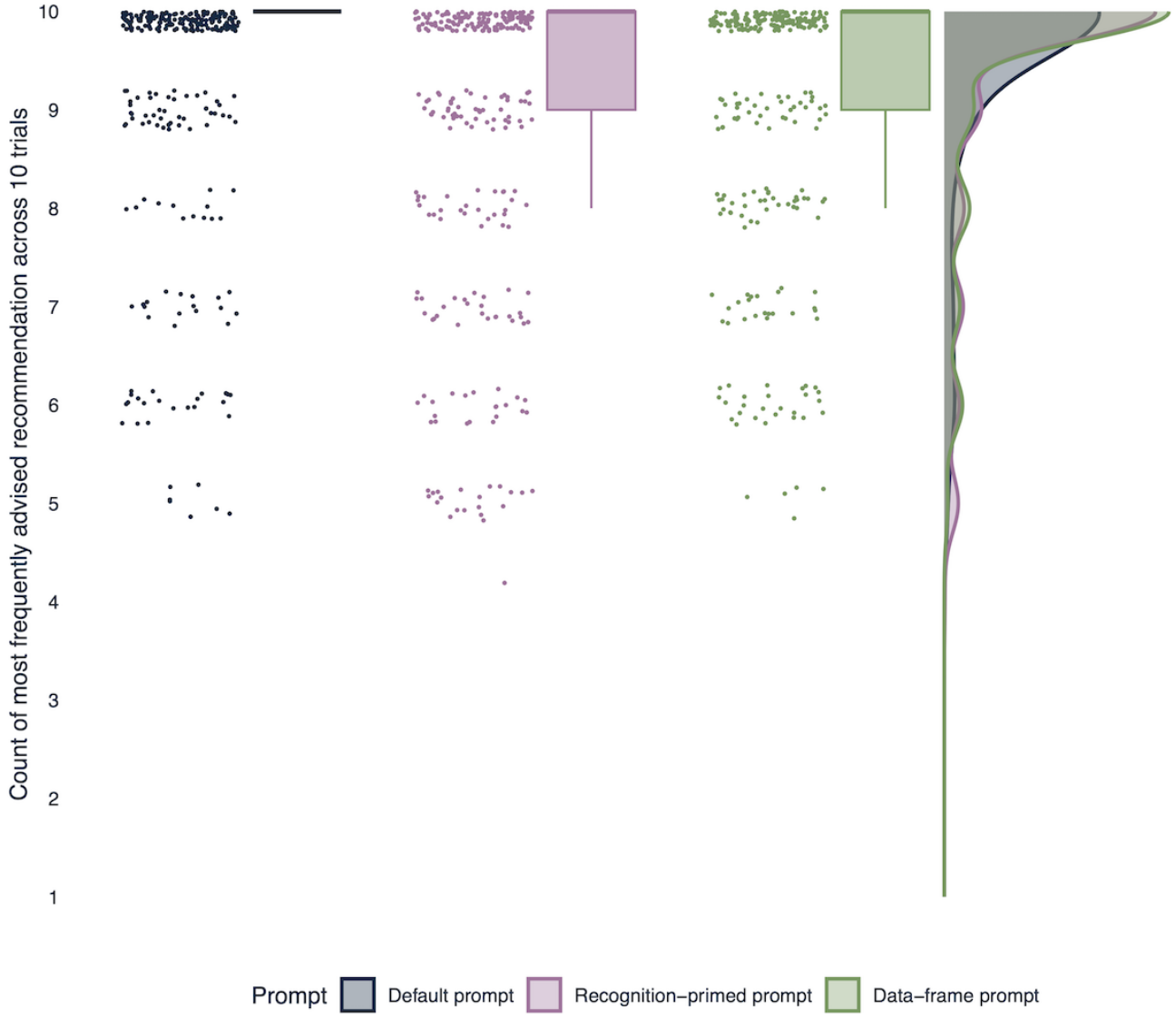
Intertrial reliability—that is, the frequency with which a vignette received the same advice from the same model across multiple trials—was comparable across all prompts, with median Fleiss κ values of 0.766 (IQR 0.706 - 0.884) for the default prompt, 0.717 (IQR 0.681 - 0.743) for the recognition-primed prompt, and 0.751 (IQR 0.725 - 0.773) for the data-frame prompt (Table 3). The results remained similar when tested with a low temperature setting (Table S5 in Multimedia Appendix 1).

Table . Intertrial reliability (Fleiss κ) of each model for each prompt.

Model	Default prompt	Recognition-primed prompt	Data-frame prompt
Overall, median (IQR)	0.766 (0.706 - 0.884)	0.717 (0.681 - 0.743)	0.751 (0.725 - 0.773)
GPT-4o	0.708	0.710	0.718
GPT-4.1	0.963	0.777	0.658
GPT-4.1 mini	0.824	0.634	0.756
o3	0.706	0.675	0.807
o4 mini	0.707	0.699	0.766
o4 mini high	0.701	0.743	0.744
GPT-5.1 Instant	0.895	0.644	0.620
GPT-5.1 Thinking	0.689	0.723	0.745
GPT-5.2 Instant	0.926	0.742	0.775
GPT-5.2 Thinking	0.851	0.821	0.839

When considering the most frequently given recommendation for each vignette by each model, all prompts yielded relatively consistent advice across multiple trials (mean 76.9%, 95% CI 72.7% - 80.7% for the default prompt; mean 66.9%, 95% CI 62.3% - 71.2% for the recognition-primed prompt; mean 71.1%, 95% CI 66.7% - 75.3% for the data-frame prompt), as shown in Figure 2. There was no statistically significant difference between the prompts in how often a specific option was recommended across trials (z=1.50, P=.13 for the recognition-primed prompt; z=0.72, P=.47 for the data-frame prompt).

Figure 2. Number of times the most frequently advised recommendation was given among the 3 prompts.



However, the tested models were more likely to provide the correct solution at least once across multiple trials when using the recognition-primed prompt (mean 82.2%, 95% CI 78.4% - 85.6%) and the data-frame prompt (mean 78.4%, 95% CI 74.4% - 82.2%) compared to the default prompt (mean 73.1%, 95% CI 68.8% - 77.2%) (Table 4). The results remained similar when tested with a low-temperature setting (Table S6 in Multimedia Appendix 1).

Table . Percentage of cases that were solved correctly at least once among 10 trials.

Model	Default prompt, mean (95% CI)	Recognition-primed prompt, mean (95% CI)	Data-frame prompt, mean (95% CI)
Overall (%)	73.1 (68.8 - 77.2)	82.2 (78.4 - 85.6)	78.4 (74.4 - 82.2)
GPT-4o (%)	77.8 (62.9 - 88.8)	84.4 (70.5 - 93.5)	80 (65.4 - 90.4)
GPT-4.1 (%)	66.7 (51 - 80)	84.4 (70.5 - 93.5)	84.4 (70.5 - 93.5)
GPT-4.1 mini (%)	55.6 (40 - 70.4)	75.6 (60.5 - 87.1)	66.7 (51 - 80)
o3 (%)	82.2 (67.9 - 92)	91.1 (78.8 - 97.5)	84.4 (70.5 - 93.5)
o4 mini (%)	86.7 (73.2 - 94.9)	88.9 (75.9 - 96.3)	86.7 (73.2 - 94.9)
o4 mini high (%)	91.1 (78.8 - 97.5)	88.9 (75.9 - 96.3)	86.7 (73.2 - 94.9)
GPT-5.1 Instant (%)	68.9 (53.4 - 81.8)	86.7 (73.2 - 94.9)	82.2 (67.9 - 92)
GPT-5.1 Thinking (%)	82.2 (67.9 - 92)	88.9 (75.9 - 96.3)	86.7 (73.2 - 94.9)
GPT-5.2 Instant (%)	60 (44.3 - 74.3)	73.3 (58.1 - 85.4)	64.4 (48.8 - 78.1)
GPT-5.2 Thinking (%)	60 (44.3 - 74.3)	60 (44.3 - 74.3)	62.2 (46.5 - 76.2)

Discussion

Principal Results

Our study investigated whether prompting strategies inspired by NDM—a field that analyzes how humans make real-world decisions under uncertainty—can improve LLM performance in ill-defined tasks such as care-seeking decisions. Our results show that both the recognition-primed and the data-frame prompts increased the accuracy of care-seeking advice across all tested models except GPT-5.2. Although this effect may partly reflect the additional reasoning process before producing an answer among nonreasoning models, we observed improvements not only in nonreasoning models but also in reasoning models that already include a reasoning process. This observation suggests that our results cannot simply be attributed to a general reasoning process. Notably, most nonreasoning models with NDM-inspired prompts outperformed traditional reasoning models using the default prompt, and reasoning models also showed significant improvements with the NDM-inspired prompts.

The greatest improvements due to the NDM-inspired prompts were seen in self-care cases, which were more often correctly identified. Nonreasoning models rarely or never provided self-care advice with the default prompt, a finding consistent with previous studies [67,69,70]. When prompted with the NDM-inspired prompts, these models began giving self-care advice and even reached a relatively high level of accuracy, up to 44%. In contrast, accuracy for the 2 included emergency cases and the included nonemergency cases showed little change, likely due to a ceiling effect, as the tested models were already highly accurate on these cases with the default prompt. Prior research suggests that self-care advice is typically given by LLMs only when a reasoning process is included and that the tendency toward risk-averse recommendations may stem from built-in safety measures [67,69]. The recognition-primed prompt explicitly instructs the model to recall similar situations (pattern matching according to the RPD model) and to forecast possible outcomes (mental simulation), which may help the model reconsider overly cautious recommendations before giving advice. Similarly, the data-frame prompt encourages the model to re-examine each initial recommendation and—if new data do not fit the initial frame—explore alternative frames, which may help identify when self-care is sufficient rather than defaulting to medical referral.

OpenAI's most recent GPT-5 model family includes an updated reasoning process [26,27]. The benefits of using NDM-inspired prompts were replicated for GPT-5.1 (for both the Instant version without a reasoning process and the Thinking version with a reasoning process), but not for GPT-5.2: self-care accuracy dropped to 0% in both GPT-5.2 Instant and GPT-5.2 Thinking and remained unchanged with NDM-inspired prompts. These results may suggest a version-level shift toward recommending professional care that prompting does not alter. This observation is unlikely to be attributable to changes in the reasoning mechanism alone, because GPT-5.1—despite also using the updated reasoning process—did not show the same decrease in self-care accuracy.

Implications

The present findings have implications for prompt engineering, artificial intelligence (AI) research, and end users. First, for prompt engineering, we suggest that, rather than relying solely on prompts built on computer science (eg, ensemble methods and decomposing), strategies derived from cognitive science, applied psychology, and HF/E—especially those based on models of human decision-making under uncertainty—may be more effective or, at least, serious competitors, particularly in domains with high ambiguity and uncertainty, such as triage or diagnostic decisions. In these ill-defined situations, we showed that a "reasoning blueprint" based on human cognition can outperform methods that simply instruct the models to reason. We acknowledge, however, that, based on our results, the benefits of NDM-inspired prompts are thus far limited to uncertain tasks. It remains to be seen how they perform on more well-defined tasks, such as text formatting or summarization.

Limitations

Although our results show a positive impact of combining NDM with prompt engineering, there are several limitations. First, we conducted a single benchmarking test within one domain, that is, care-seeking advice. Although this is a typical real-world decision task with high uncertainty and a common use case for LLMs [68,76-80], it remains unclear whether our findings generalize to other tasks or domains with varying levels of ambiguity and/or uncertainty. Second, the low sample size for emergency cases leads to unstable accuracy estimates, and no safety conclusions should be derived from the data presented here. Third, we limited our evaluation to LLMs that are currently integrated into ChatGPT. We made this decision to assess practical impact for users; however, it is unclear whether these results would hold true for the broader range of LLMs available or in development. In particular, future research should test whether similar results can be achieved with smaller models and limited context windows, given that the reasoning process increases token requirements.

The NDM-inspired prompts themselves present another limitation. These prompts are computationally more expensive to run than standard user inputs because they add a reasoning output before giving advice. Although this may not affect individual users, it could increase operational costs for developers integrating such prompts, especially compared to nonreasoning models. We recommend that any potential performance gains from NDM-inspired prompting be carefully weighed against increased costs on a case-by-case basis.

Next, we did not include participants who interacted with the LLMs directly. Instead, we used a highly controlled setup in which each model was prompted repeatedly using standardized prompts. In real-world use, however, users' prompts vary substantially in both content and quality [4,70,93]. Accordingly, the present study was designed to test whether NDM-inspired prompts can improve model accuracy under controlled conditions; we cannot infer that these prompts would translate into improved user decisions or higher-quality outputs in everyday use. This work should, therefore, be interpreted as a technical evaluation of model behavior under controlled inputs rather than as a clinical validation study. Depending on the

intended use, LLMs may be regulated as Software as a Medical Device and may, therefore, require additional evidence that is outside the scope of the present study. Recent work on differing user inputs and adversarial attacks in chatbots shows that they can produce unsafe outputs depending on the specific prompts, which further demonstrates that more rigorous and use-case-specific safety evaluations are needed before deployment [94,95]. Future studies should therefore conduct user studies to examine whether NDM-inspired prompts also yield better recommendations and decision support for users in real-world settings, and to determine how NDM-inspired prompts may be used to prevent adversarial attacks.

Finally, the prompts tested here were based on only 2 decision-making models. There are other models that could serve as inspiration for prompt development, such as the decision ladder or heuristic decision models [51,96]. Moreover, domain-specific decision-making models may be even better suited for certain use cases. For care-seeking advice, no such model currently exists to explain how humans make these decisions. However, the development of such a model could be helpful to develop even more targeted prompting strategies to further increase LLM performance.

Future Research

This study is among the first to combine NDM and AI-based decision support systems to foster more naturalistic decision support. Our findings provide a foundation for future work by demonstrating that real-world human reasoning strategies can improve the accuracy of LLMs. Building on these results, future work could examine how NDM and AI can be combined to support users. For example, prompting LLMs to use reasoning processes that reflect human decision-making could open a new direction for explainable AI. Unlike traditional explainable AI methods that focus on feature importance, providing explanations based on human-like pattern recognition and mental simulation may increase trust and help users identify potential mistakes in the reasoning process. Prior research has shown that users critically assess, rather than blindly follow, AI advice [4]. Giving users an NDM-inspired reasoning approach may support this evaluation more than providing advice with a post hoc explanation.

NDM-inspired prompts may also improve human-AI collaboration: When humans and AI share a conceptual language (consisting of frames, pattern matching, and mental simulation), it may become easier for users to integrate AI advice into their own reasoning. For example, physicians could review the frames used by the LLM, add new data points, and let the AI simulate whether these fit the frame. Conversely, the AI could make predictions based on its frame, which the physician can cross-check with clinical data. An AI would thus not only give a final recommendation but also provide support in hypothesis generation, data gathering, and hypothesis testing [97,98].

Next, NDM-inspired prompting could also be used for education and training. LLMs could serve as interactive tools for medical students, allowing them to practice decision-making using the RPD model alongside the AI by comparing their mental simulations with those of the model. The AI could then provide feedback on differences in their respective frames.

More broadly, future work should move beyond technical benchmarking toward evaluation designs aligned with Software as a Medical Device expectations by predefining the intended use case and testing performance and safety prospectively in real-world settings. In this context, NDM may be treated as a theoretical basis for uncertainty management, and future studies can test whether NDM-based prompts reduce failures across different user inputs and adversarial attacks.

Conclusions

In this study, we showed that applying models from NDM to prompt LLMs can improve performance in highly uncertain and ambiguous care-seeking tasks. Both NDM-inspired prompts tested here increased overall accuracy across both reasoning and nonreasoning models, with the greatest improvement in self-care recommendations, while maintaining high accuracy in the 2 included emergency cases and all included nonemergency cases. These findings may open up a new strategy for prompt engineering: rather than relying on prompts derived from computer science, prompts that build on NDM models or related models from applied psychology and HF/E, which represent how humans make sense of uncertainty, may be more effective in ill-defined tasks. As LLMs and other AI tools are increasingly adopted in safety-critical and everyday applications, NDM-inspired prompting may offer a strategy for making AI more useful for real-world decision-making.

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Data Availability

The data can be accessed via Zenodo [99].

Conflicts of Interest

MK is an associate editor for *JMIR Public Health and Surveillance*.

Multimedia Appendix 1
Additional accuracy and sensitivity analyses.
[DOCX File, 30 KB - biomedeng_v11i1e88053_app1.docx]

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Abbreviations

AI: artificial intelligence
HF/E: human factors and ergonomics
LLM: large language model
NDM: naturalistic decision-making
RPD: recognition-primed decision-making
TRIPOD: Transparent Reporting of a Multivariable Model for Individual Prognosis or Diagnosis

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Psychosocial Stress in the Chinese Community: Speech Analytics Through Linguistic and Acoustic Fusion Using Machine Learning

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Abstract

Background: Family caregivers experience significant stress due to intensive caregiving activities, making them highly susceptible to adverse psychosocial health conditions. Early detection of this stress is crucial for timely interventions to prevent disease progression and long-term disability.

Objective: This study aimed to develop and validate the Linguistic and Acoustic Speech Analytics Program, a novel machine learning approach capable of providing a fusion analysis of linguistic and acoustic speech features to enhance the effectiveness of psychosocial stress assessment.

Methods: This quantitative study analyzed speech data collected from 100 Chinese family caregivers. Participants responded to 12 open-ended questions, and their voices were recorded for linguistic and acoustic feature extraction. Various machine learning classifiers, including support vector machine, were developed to process speech data. A key methodological step was the application of an orthogonalization procedure to decorrelate acoustic features from linguistic features before fusion analysis. The classifiers were then trained to evaluate psychosocial stress levels based on the processed and fused linguistic and acoustic speech features. Model performance was measured using receiver operating characteristic-area under the curve, F_1-score, and accuracy.

Results: The linear support vector machine model emerged as the top performer, achieving a receiver operating characteristic-area under the curve of 78.28%, an F_1-score of 75.27%, and an accuracy of 73%. These results demonstrate the model's strong capability in identifying stressed participants based on their speech. Critically, the fusion of linguistic and acoustic features significantly outperformed models using either feature type alone. Furthermore, the orthogonalization procedure proved essential, as decorrelating features before fusion markedly enhanced classification accuracy compared to using non-orthogonalized features.

Conclusions: This study demonstrates that fusion analysis of linguistic and acoustic features effectively identifies psychosocial stress among family caregivers. It also emphasizes the importance of proper feature processing when combining multiple features extracted from the same audio sample. These findings provide valuable insights for developing machine learning models for psychosocial stress assessment and addressing various psychosocial conditions in different contexts, supporting population mental health management.

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KEYWORDS

caregivers; digital health; psychosocial health; speech analytics; text analytics

Introduction

Psychosocial wellness, encompassing the intricate interplay of mental, emotional, social, and spiritual well-being, is essential for overall health. However, the increasing pressures of modern life expose individuals to various stressors, significantly contributing to a rise in psychosocial conditions, which involve a broad category of mental health disturbances and social behavioral patterns that can impair daily functioning [1]. The World Health Organization (WHO) reports that one in eight people globally live with a mental health condition, with anxiety and depression being the most prevalent [2-4]. If left

unaddressed, these issues can escalate into severe mental disorders, leading to significant disability. Mental disorders account for 16% of global disability-adjusted life years and impose an annual economic burden of approximately US $5 trillion (2019 dollars) [5], highlighting the profound effects of psychosocial conditions on individuals, families, and society.

Early detection and intervention are crucial to the effective treatment of psychosocial conditions [6]. However, 75% of individuals in need, particularly in low- and middle-income countries, do not receive adequate interventions [3]. A major obstacle is the lack of easily accessible and efficient assessment services. Currently, the gold standard assessment method involves comprehensive individual interviews conducted by specialists using validated questionnaires, which is time-consuming and resource-intensive [7]. Furthermore, these assessments rely on clients' responses that can be subjective and unreliable. For instance, public stigma surrounding psychosocial conditions may lead clients to provide socially acceptable answers rather than truthful ones [8,9]. Individuals may also lack complete self-awareness, making accurate self-reporting challenging [10]. Consequently, identifying subtle signs of psychosocial conditions often relies heavily on the assessor's experience, impacting both the efficiency and accuracy of evaluations. Thus, there is an urgent need to develop an automated, scalable system that enables objective and efficient assessment of psychosocial conditions.

Speech, as an information-rich signal conveying unique thoughts and emotions, can serve as a behavioral marker with which to assess psychosocial health [11]. Speech has long been recognized as a process requiring complex motor coordination, involving more than 100 muscles, and supported by an extensive network of brain regions that handle auditory, somatosensory, and visual information, along with language comprehension and production [12]. Hence, spoken communication is a valuable window into the mind, creating opportunities for technologies that capture and process speech in order to evaluate psychosocial health. Recent advances in digital technologies and machine learning provide a foundation for developing automated systems to assess psychosocial health through speech analytics [6].

Speech consists of linguistic and acoustic features, both known to indicate mental disorders [13]. Linguistic features include the frequency of specific words and phrases, often analyzed through text extraction, topic modeling, and word embeddings. The elevated use of certain terms has been identified as a marker of anxiety, depression, and suicidal ideation [14-16]. Acoustic features encompass various voice quality characteristics, such as pitch, intensity, speech rate, prosody, and jitter. Research indicates that patients with depression tend to exhibit a lower pitch, more monotonous speech, reduced sound intensity, and slower speech rates [17,18]. While linguistic and acoustic features can reflect an individual's psychosocial status, many reported speech analytics systems focus on only one feature. Furthermore, despite the insights gained from speech analytics in assessing mental health conditions, few studies have specifically explored its application in the assessment of psychosocial stress.

Stress is a common initial indicator of psychosocial issues and a known risk factor for numerous mental and physical health problems [19,20]. Identifying stress is therefore crucial for early intervention and prevention of severe mental disorders. While speech analytics has shown potential for detecting stress, most studies focused on analyzing either linguistic or acoustic features alone, resulting in suboptimal accuracy for practical applications in psychosocial services [14,21].

Recent research suggests that the fusion analysis of linguistic and acoustic features can enhance mental health assessments, including the identification of suicidal ideation and depression [11,22]. However, existing studies often rely on voice recordings obtained by directly inquiring about sensitive topics. This approach can lead to misleading results, as participants may be reluctant to disclose their true psychosocial status due to social stigma. To overcome this, we conducted this study in a real-world community setting, where social workers asked participants nonsensitive and open-ended questions about family life, allowing them to express their true feelings and reducing the risk of response bias. To the best of our knowledge, this is the first study of its kind conducted within a Chinese community.

To address the challenge of the automatic stress-level classification problem, we developed the Linguistic and Acoustic Speech Analytics Program (LASAP) to provide a comprehensive fusion analysis of both linguistic and acoustic features to improve psychosocial stress classification. This study applies the LASAP to detect psychosocial stress among family caregivers—a group particularly vulnerable to significant stress due to physical, emotional, and financial challenges associated with family caregiving. Recognizing signs of stress and implementing supportive measures can help caregivers maintain their psychosocial health and overall quality of life.

Another challenge in current fusion studies is the lack of robust methods for processing linguistic and acoustic features before they are combined. This step is crucial because features extracted from the same speech sample are naturally correlated, and using them together without proper processing can lead to information redundancy and an increased risk of model overfitting [23]. For instance, when an individual states, "I feel overwhelmed and stressed every day," the words "overwhelmed" and "stressed" serve as linguistic indicators of stress. Simultaneously, the acoustic features extracted might reflect a higher pitch when saying "overwhelmed" and a louder volume when emphasizing "stressed," both conveying emotional intensity. This natural correlation between linguistic and acoustic features may hinder subsequent analyses. If these features are analyzed together without decorrelation, the emotional state indicated by both might be overemphasized, potentially leading to overfitting in the developed automated system [24]. Therefore, we implemented a novel orthogonalization procedure to decorrelate the acoustic features from the linguistic features [25].

Using well-processed features, the LASAP successfully distinguished between family caregivers with different stress statuses. By integrating both linguistic and acoustic features, it achieved higher accuracy in stress detection compared to

analyses of either feature alone. Additionally, the LASAP streamlines data collection by asking a limited number of targeted general questions, minimizing interview time, and improving assessment efficiency. This automated program not only enables accurate and efficient evaluations but also holds promise for delivering accessible and affordable psychosocial services through digital health technologies. This research highlights the potential of fusion analysis to enhance the accuracy of early psychosocial assessments and underscores the importance of proper feature processing for effective analysis.

The goal of the LASAP differs significantly from that of our previously developed method, the Automatic Speech Analytic Program (ASAP) [14]. The LASAP aims to predict an individual's stress level through the fusion analysis, which combines both linguistic and acoustic features, and the orthogonalization procedure. This approach involves building a machine learning classifier trained on a set of labeled data and evaluated on a separate, unseen testing dataset. In contrast, the ASAP utilizes a clustering technique to split a group of individuals into low-stress status and high-stress status. However, due to the splitting nature of the clustering technique, the ASAP requires all individuals to be present at the start of the analysis. If a new, unseen individual is introduced after the analysis has begun, that individual cannot be categorized. Additionally, the ASAP relies solely on linguistic features for its analysis and does not incorporate acoustic features.

Methods

Study Design and Participants

Family caregivers from diverse backgrounds were recruited from a nonprofit organization providing integrated family and community services in Hong Kong. A total of 100 family caregivers were approached and recruited by registered social workers, who explained the study and obtained signed informed consent from participants. Participation was entirely voluntary.

Stress levels of the 100 caregivers were assessed using the validated Caregiver Burden Inventory (CBI) [26]. The CBI is a 24-item self-report scale that evaluates caregiver stress through a multidimensional approach, consisting of 5 subscales: time dependence, developmental, physical, social, and emotional burden. This study adopted a validated Chinese version of the CBI, which demonstrated a Cronbach α of 0.95 [27]. Participants assessed each item using a 5-point Likert scale, where "0" indicates "not at all descriptive" and "4" indicates "very descriptive." Higher scores reflect greater caregiver stress. A total score of 36 or lower indicates low levels of stress, whereas a score above 36 indicates high levels of stress. Ultimately, 44 caregivers were classified as low stress and 56 as high stress. Qualified social workers from the nonprofit organization, who were familiar with the participants, agreed with the classification based on their understanding of the participants.

In addition to completing the CBI, all participants were asked 12 open-ended questions about their families and feelings. Their responses were recorded for training and testing the LASAP machine learning model. Existing literature suggests that open-ended questions provide more information than read speech tasks, and hence, they were adopted in this study [28]. The 12 questions, designed to explore family resilience, are listed in Table S1 in Multimedia Appendix 1. They cover 3 broad processes of Walsh family resilience theory: family belief systems, organizational patterns, and communication patterns. Family belief systems indicate the ability to overcome crises by finding meaning in adversity, maintaining a positive outlook, and fostering spiritual beliefs. Organizational patterns reflect supportive family relationships that are flexible, connected, and accessible to social networks and economic resources. Communication patterns denote the capacity of family members to communicate effectively, ensuring clarity, open emotional expression, and problem-solving in challenging situations. Previous studies have shown that family resilience is closely related to caregiver stress, with higher levels of family resilience correlating with lower stress levels [29]. These nonsensitive questions allow participants to discuss their daily lives casually and express their true feelings, making them a less intrusive approach than directly querying about caregiver stress. Since family resilience is strongly correlated with stress levels, these questions can effectively reflect participants' stress burdens [30]. From the responses of the 100 participants, we identified 53 keywords (representing 53 linguistic features) across 14 different topics (see Table S2 in Multimedia Appendix 1).

Ethical Considerations

This project was approved by the Human Participants Research Panel of The Hong Kong University of Science and Technology (reference number 252). The research followed the Declaration of Helsinki ethical principles. All participants received detailed information about the study's aims and procedures and provided informed consent. Participants had the right to withdraw from the study at any time, and participation was entirely voluntary. Data were anonymized, securely stored, and used solely for research purposes.

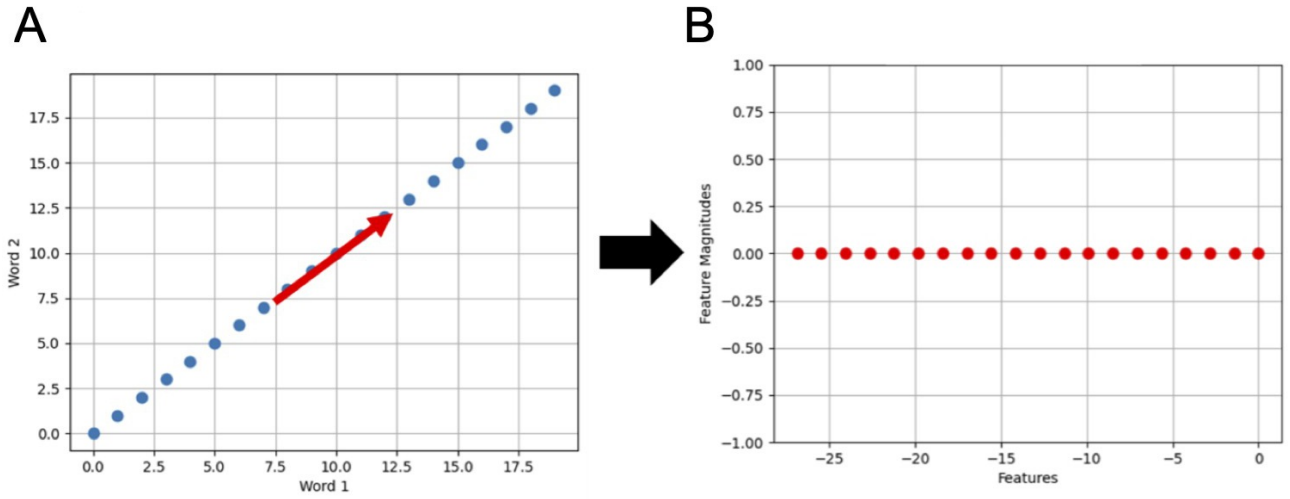
LASAP Development

The LASAP was developed to optimize speech analytics with regard to assessing psychosocial stress. The program independently extracts linguistic and acoustic features from family caregivers' speech. Linguistic features were derived by converting speech to text and analyzing word frequencies, with principal component analysis (PCA) applied to remove redundant information and retain meaningful features. A screening process identified 53 keywords linked to stress and family resilience topics based on the Walsh theory. Acoustic features were extracted using signal processing techniques via the openSMILE (audEERING GmbH) toolkit, generating 6503 features based on low-level descriptors (LLDs), such as "shimmer," which measures vocal stability and emotional deficits. To prevent overlapping information between linguistic and acoustic features, an orthogonalization procedure was used to decorrelate them, ensuring independent contributions to the analysis. This approach improved the distinction between high-stress and low-stress samples, facilitating a more accurate assessment of caregiver stress and resilience.

Linguistic Feature Extraction and Processing

After collecting interview audio recordings from family caregivers, we converted their speech into text transcripts using the Google Cloud Speech application programming interface. The text was analyzed by counting the frequency of specific words and phrases. To eliminate redundant information, we applied PCA to remove words that carry the same sentiment, are frequently repeated, or are highly correlated with other words [31]. This process ensures that the dataset retains only unique and relevant linguistic features, enhancing the robustness and meaningfulness of subsequent analyses. Figure 1 demonstrates how PCA eliminates redundant information. In Figure 1A, the frequency counts of 2 words are shown. These words appear in all documents with the same frequency, resulting in a strong correlation between them. This correlation is visually represented as a diagonal line in the figure. PCA addresses this redundancy by identifying the diagonal direction as the primary axis (x-axis) and rotating the entire system to align with this new axis. This transformation is illustrated in Figure 1B, where the x-axis corresponds to the diagonal direction from Figure 1A. By doing so, PCA reduces the dimensionality of the representation, using only 1 dimension instead of 2 to capture the same information. This effectively removes redundant data.

Figure 1. Illustration of the removal of redundant information using principal component analysis (PCA): (A) frequency counts of 2 words (before applying PCA) and (B) the results after applying PCA.



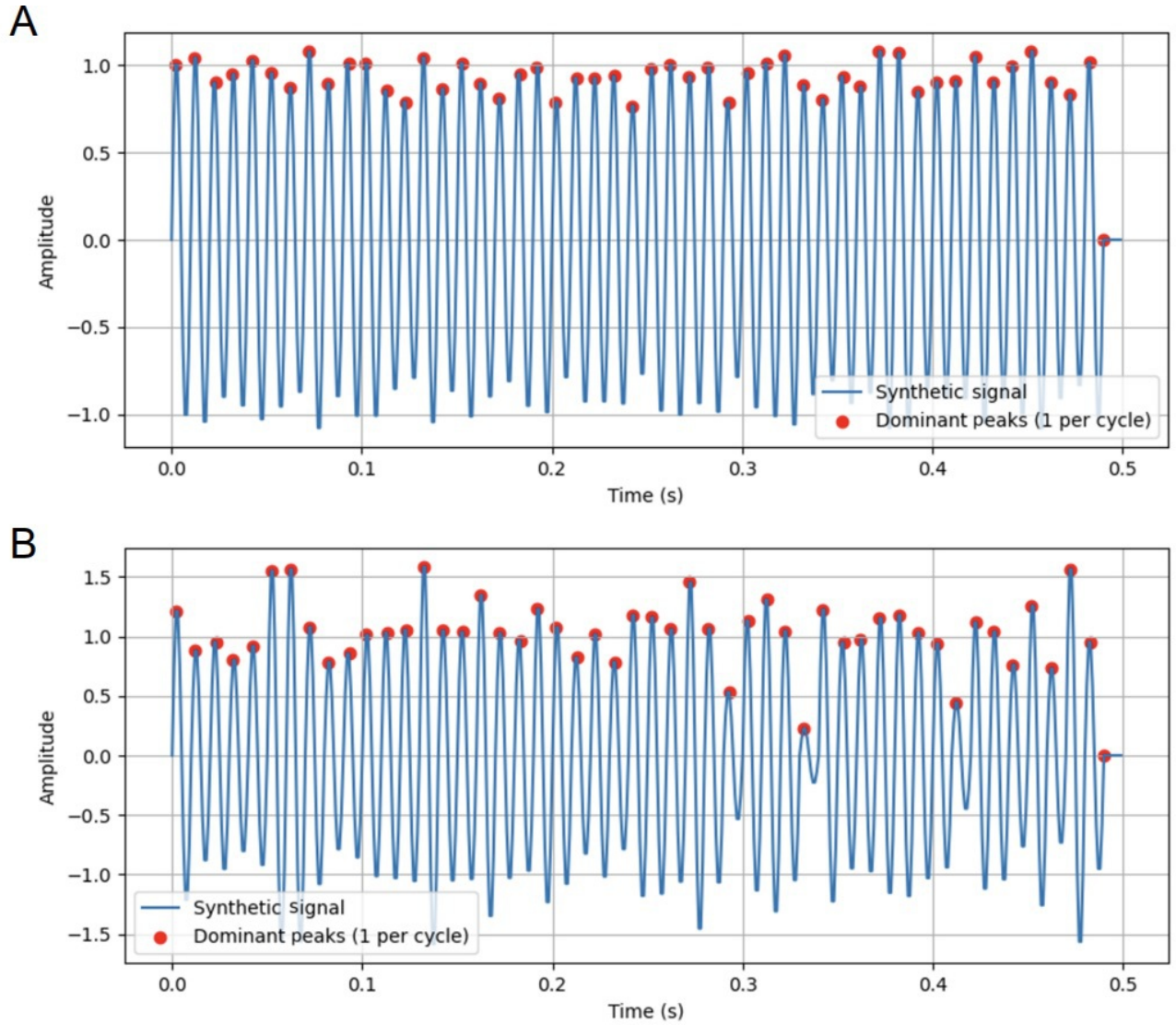
We applied a screening process to select the 53 keywords from 2683 words that were extracted from all of the 100 text scripts. First, words or phrases were selected if they appeared 2 times or more and if they were related to a list of 14 family resilience topic categories identified through topic modeling [32]. After this screening process, 53 keywords or phrases were selected, related to the 14 different topics aligned with the 3 processes of the Walsh family resilience theory. This topic identification process facilitates a better classification of relevant words and contributes to an accurate assessment of caregiver stress, which is closely related to family resilience [30]. The frequency count of these 53 keywords among caregivers with high-stress or low-stress levels is listed in Table S2 in Multimedia Appendix 1 and serves as the linguistic features used in subsequent analyses.

Acoustic Feature Extraction and Processing

We captured the acoustic features from the audio recordings using popular signal processing techniques, including the Fourier transform and spectral methods, implemented through the use of the Python package openSMILE [33]. Table S3 in Multimedia Appendix 1 presents a list of acoustic subsets adopted by INTERSPEECH 2016 ComParE (Computational Paralinguistics Challenge), built upon 65 LLDs that characterize the temporal and spectral properties of the acoustic signal [34]. Since the LLDs of an acoustic signal are themselves signals, we derive acoustic features by considering various mathematical and statistical characteristics of these LLDs. These characteristics include the simple moving average of an LLD, first-order derivatives, IQRs, minimum positive values, segment length SD, mean and SD of peak distances, mean peak relative height, flatness, rise time, skewness, left center time, and centroid. In total, we utilized 6503 acoustic features for this study.

LLDs have been used to identify various emotional states. In this context, we focus on shimmer as an example. Shimmer quantifies the vocal stability of a sound wave over time [35]. Irregular vocal fold vibrations—often associated with emotional deficits—can lead to variations in shimmer. For instance, a depressed individual may speak with uneven loudness, reflecting instability in vocal amplitude. To illustrate this concept, we consider the synthetic signals as shown in Figure 2. The 2 figures represent wave cycles of speech, where the amplitudes of the wave shown in Figure 2A are more consistent compared to those in Figure 2B. Amplitude corresponds to the loudness of a voice; larger amplitudes indicate louder sounds. In the case of a depressed individual, uneven loudness may result in greater amplitude variations (as in Figure 2B). Shimmer provides a method to quantify this variation by measuring fluctuations in the peaks of the waveform. In doing so, shimmer effectively captures the stability of a voice, which can serve as an indicator of emotional deficits. However, in real-world scenarios, sound waves often vary in length, resulting in differing numbers of peaks and shimmer values. To standardize the number of features extracted, we calculate mathematical and statistical characteristics of the shimmer values, such as the minimum, maximum, quantiles, and other summary statistics.

Figure 2. Illustration of shimmer, a low-level descriptor (LLD): (A) synthetic signal with low shimmer and (B) synthetic signal with high shimmer.

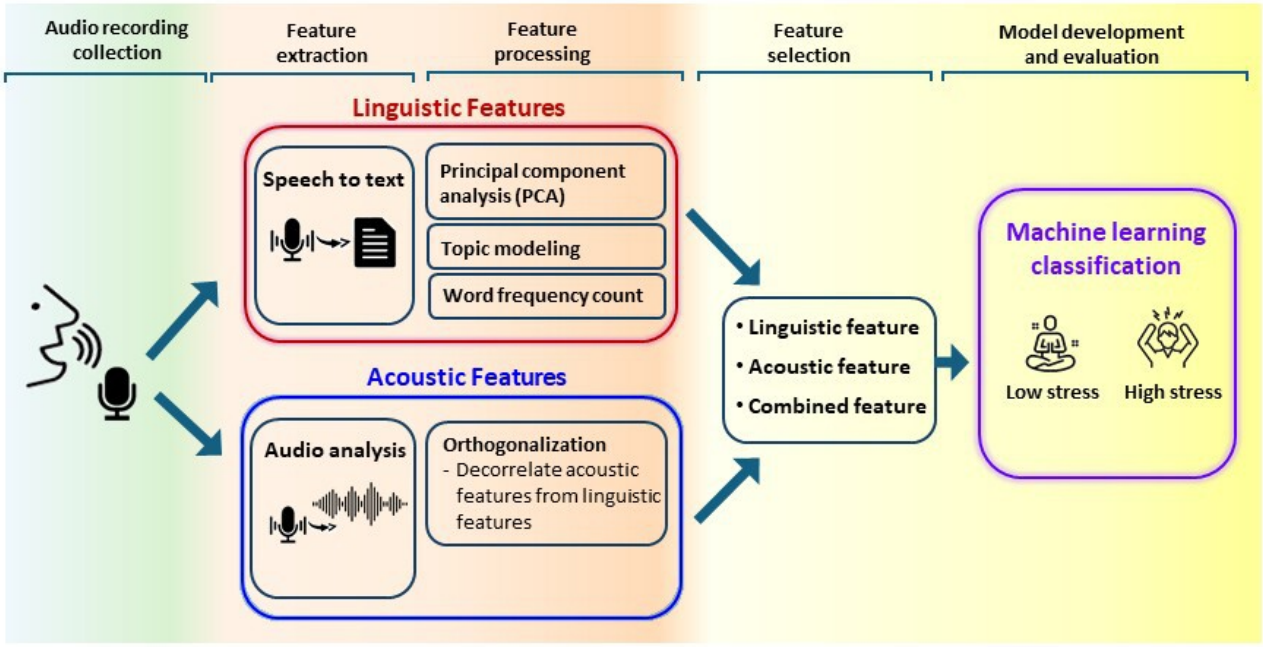


Subsequently, we adopted the novel application of an orthogonalization procedure to decorrelate the acoustic features from the linguistic features. As we extracted both linguistic and acoustic features from the same audio recordings, they may contain overlapping information. For instance, when a family caregiver says, "I feel overwhelmed and stressed every day," the emotion-related words "overwhelmed" and "stressed" are counted as linguistic features indicating stress. At the same time, the acoustic features extracted from the audio may include a higher pitch when saying "overwhelmed" and a louder volume when emphasizing "stressed," which also convey emotional intensity. This phenomenon highlights a natural correlation between linguistic and acoustic features within a speech sample. If these features were analyzed together without decorrelation, the analysis might overemphasize the emotional state indicated by both. Therefore, we performed the orthogonalization procedure to decorrelate them. After orthogonalization, we found that the acoustic features of the high-stress sample are significantly diminished. This reduction may suggest that linguistic features carry substantial high-stress information, and orthogonalization removes this emotional information from the high-stress samples. Conversely, linguistic features seem to carry minimal low-stress information, resulting in a smaller impact of orthogonalization on the low-stress sample.

Orthogonalization is a mathematical process used to create a set of directions (or vectors) that are perpendicular to each other. This concept is illustrated in Figure S1 in Multimedia Appendix 1. The red dots represent an acoustic feature, while the green triangles represent a linguistic feature. As shown, these 2 directions are not perpendicular to each other; in other words, they are correlated and contain redundancy. To eliminate this redundancy, we apply a transformation to the acoustic feature, resulting in the blue line in Figure S1 in Multimedia Appendix 1. It can be observed that the blue line is now perpendicular to the green triangles. This transformation simplifies data analysis because each new feature represents a distinct direction of variation, free of redundancy.

An overview of the LASAP pipeline is illustrated in Figure 3.

Figure 3. Overview of the Linguistic and Acoustic Speech Analytics Program (LASAP) pipeline.



Machine Learning Classifier Models

Various machine learning classifier models, including linear support vector machine (SVM-linear), polynomial SVM (SVM-poly), radial basis function SVM (SVM-RBF), sigmoid kernel SVM (SVM-sigmoid), AdaBoost, ExtraTrees, k-nearest neighbor, and random forest, were trained using double cross-validation with a 10-fold outer cross-validation and a 5-fold inner cross-validation to differentiate psychosocial stress status based on the combined linguistic and acoustic features. Hyperparameters varied across settings, and those demonstrating the best performance in regard to the validation set are selected and listed in Table S4 in Multimedia Appendix 1.

We use F_1-score, accuracy, and receiver operating characteristic-area under the curve (ROC-AUC) as evaluation metrics [36-38]. F_1-score is the harmonic mean of precision and recall. The formula is as follows:

$$\text{F1-score} = \frac{2TP}{2TP+FP+FN} \times 100\% \quad (1)$$

where TP, FP, and FN are the true positives, false positives, and false negatives, respectively. In the F_1-score, true negatives are omitted. Accuracy is the proportion of correct predictions among the total number of cases examined. The formula is as follows:

$$\text{Accuracy} = \frac{TP+TN}{TP+TN+FP+FN} \times 100\% \quad (2)$$

ROC-AUC reports the area under the receiver operating characteristic curve from prediction scores. The receiver operating characteristic curve plots the true positive rate (TPR) ($=\frac{TP}{TP+FN}$) against the false positive rate ($=\frac{FP}{TN+FP}$) at various threshold settings.

Results

Participants and Feature Characteristics

This study analyzed audio recordings from 100 family caregivers, with 44 classified as low stress and 56 as high stress. No statistically significant differences were observed between the 2 groups regarding demographic data.

The linguistic and acoustic features of the caregivers' speech were extracted. The linguistic features used for machine learning analysis included frequency counts for 53 stress-indicating words, categorized into 14 different topics (Table S2 in Multimedia Appendix 1). The acoustic features consisted of 6503 characteristics, such as pitch, speech rate, and voice quality, organized into 65 subsets (Table S3 in Multimedia Appendix 1).

Following a common practice of training a machine learning classifier, a double cross-validation technique was employed. The entire dataset was divided into 2 parts using cross-validation. The first one (training set) was to train the classifier. The second one (validation set) was used to find the hyperparameters of a classifier. The last one (testing set) was to evaluate the performance of the trained classifier. All the preprocessing steps were conducted in the training set. This included applying PCA to the linguistic features and eliminating redundant information among them [31]. An orthogonalization procedure was applied to the acoustic features to decorrelate them from the linguistic features. Both linguistic and acoustic features were then combined as an input for the machine learning classifier. The hyperparameters of the classifier are determined using the validation set. The trained classifier, together with the selected hyperparameters, was evaluated using the testing set. The detailed procedure is shown in Table S5 in Multimedia Appendix 1.

Model Performance

All machine learning classifier models successfully distinguished stress levels based on the combination of linguistic and acoustic features (Table 1). Among them, the SVM-linear, SVM-sigmoid, SVM-RBF, and SVM-poly models outperformed the others, achieving ROC-AUC values of 78.28%, 78.77%, 76.65%, and 75.43%, respectively. The best-performing model, SVM-linear, not only achieved a high ROC-AUC value but also recorded the best F_1-score and accuracy score, which were 75.27% and 73%, respectively.

Table . Performance of classifiers under combined linguistic and acoustic features.

Classifier	F_1-score (SD), %	Accuracy (SD), %	ROC-AUC[a] (SD), %
SVM-sigmoid[b]	71.67 (4.08)	56 (4.9)	78.77 (14.32)
SVM-linear[c]	75.27 (11.53)	73 (13.45)	78.28 (13.67)
SVM-RBF[d]	71.67 (4.08)	56 (4.9)	76.65 (14.16)
SVM-poly[e]	71.67 (4.08)	56 (4.9)	75.43 (20.85)
KNN[f]	70.83 (4.17)	57 (6.4)	63.34 (13.17)
Random forest	71.31 (3.93)	56 (4.9)	61.17 (18.28)
AdaBoost	71.67 (4.08)	56 (4.9)	59.66 (13.98)
ExtraTrees	71.31 (3.93)	56 (4.9)	52.47 (22.87)

[a]ROC-AUC: receiver operating characteristic-area under the curve.

[b]SVM-sigmoid: sigmoid kernel support vector machine.

[c]SVM-linear: linear support vector machine.

[d]SVM-RBF: radial basis function support vector machine.

[e]SVM-poly: polynomial support vector machine.

[f]KNN: k-nearest neighbor.

Predictive Power of Feature Settings

In addition to the combined features, 2 additional feature settings, such as linguistic features only and acoustic features only, were applied to the machine learning training and testing. The ROC-AUC, F_1-score, and accuracy values for the 4 best-performing classifier models across different feature settings are presented in Table 2. For the best-performing SVM-linear model, using linguistic features alone and acoustic features alone achieved ROC-AUC values of 76.68% and 60.92%, respectively. In contrast, the combination of linguistic and acoustic features achieved the highest ROC-AUC of 78.28%, demonstrating that the fusion analysis provides a clear predictive advantage. This pattern was consistent across other top SVM models (SVM-sigmoid, SVM-RBF, and SVM-poly). The results presented in Table 2 also reveal a performance imbalance in most models, where high F_1-scores are not matched by similarly high accuracy. While this phenomenon appears in most models, it is not observed in the top-performing SVM-linear model. This discrepancy arises because most classifiers performed better for the high-stress status and were biased toward the TPR. In contrast, the SVM-linear model demonstrated a balanced performance across both high-stress and low-stress statuses, achieving strong results for both the TPR and the true negative rate.

Table . Performance of classifiers under different feature settings.

Classifier and feature setting	F_1-score (SD), (%)	Accuracy (SD), (%)	ROC-AUC[a] (SD), (%)
SVM-sigmoid[b]			
Combined (linguistic + acoustic)	71.67 (4.08)	56 (4.9)	78.77 (14.32)
Linguistic only	70.32 (11.35)	62 (13.27)	78.7 (13.02)
Acoustic only	70.01 (13.88)	60 (16.73)	57.58 (26.18)
SVM-linear[c]			
Combined (linguistic + acoustic)	75.27 (11.53)	73 (13.45)	78.28 (13.67)
Linguistic only	71.69 (16.28)	70 (16.12)	76.68 (17.19)
Acoustic only	56.95 (25.17)	54 (22)	60.92 (26.56)
SVM-RBF[d]			
Combined (linguistic + acoustic)	71.67 (4.08)	56 (4.9)	76.65 (14.16)
Linguistic only	71.69 (16.28)	70 (16.12)	76.68 (17.19)
Acoustic only	71.67 (4.08)	56 (4.9)	62.17 (21.8)
SVM-poly[e]			
Combined (linguistic + acoustic)	71.67 (4.08)	56 (4.9)	75.43 (20.85)
Linguistic only	72.82 (5.82)	61 (7)	75.15 (19.81)
Acoustic only	71.67 (4.08)	56 (4.9)	51.83 (26.45)

[a]ROC-AUC: receiver operating characteristic-area under the curve.

[b]SVM-sigmoid: sigmoid kernel support vector machine.

[c]SVM-linear: linear support vector machine.

[d]SVM-RBF: radial basis function support vector machine.

[e]SVM-poly: polynomial support vector machine.

Importance of Acoustic Feature Processing

The acoustic features—used alongside linguistic features to achieve optimal predictive power—underwent an orthogonalization procedure to decorrelate them from the linguistic features. Given the natural correlation between these feature types in speech, this decorrelation process is essential to enhancing predictive performance. Such correlations can result in overlapping information when extracting features from the same audio recordings, which may lead to an overemphasis on the emotional state indicated by both feature types. To address this, we employed a novel orthogonalization procedure to ensure that the acoustic features were decorrelated from the linguistic features. Following this procedure, the acoustic features became orthogonal to the linguistic features, confirming successful decorrelation.

When the SVM-linear model was applied to the combined features without orthogonalization, it produced an ROC-AUC value of 57.22%—significantly lower than the optimal ROC-AUC value of 78.28% (Table 3). To verify the statistical significance, we compared the performance with and without orthogonalization using bootstrapping. We applied double cross-validation 100 times with different random seeds. We then computed the lower and upper CIs using the following formula.

Table . Performance of classifiers under combined features with or without processing the acoustic features through orthogonalization.

Classifier and orthogonalization	F_1-score (SD), %	Accuracy (SD), %	ROC-AUC[a] (SD), %
SVM-sigmoid[b]			
Yes	71.67 (4.08)	56 (4.9)	78.77 (14.32)
No	70.9 (14.39)	61 (17)	62.93 (23.43)
SVM-linear[c]			
Yes	75.27 (11.53)	73 (13.45)	78.28 (13.67)
No	60.95 (24.75)	60 (21.91)	57.22 (22.96)
SVM-RBF[d]			
Yes	71.67 (4.08)	56 (4.9)	76.65 (14.16)
No	69.26 (9.29)	60 (10.95)	60.9 (25.68)
SVM-poly[e]			
Yes	71.67 (4.08)	56 (4.9)	75.43 (20.85)
No	50.13 (21.19)	50 (17.32)	58.35 (27.53)

[a]ROC-AUC: receiver operating characteristic-area under the curve.

[b]SVM-sigmoid: sigmoid kernel support vector machine.

[c]SVM-linear: linear support vector machine.

[d]SVM-RBF: radial basis function support vector machine.

[e]SVM-poly: polynomial support vector machine.

(3)Evaluation metric with orthogonalization−Metric evaluation without orthogonalization

The CIs for the 3 evaluation metrics are given in Table 4. The 2.5th percentile values for all 3 metrics are larger than 0, and thus, the performance with orthogonalization is better than without.

Table . CIs of the linear support vector machine (SVM-linear) model with and without processing the acoustic features through orthogonalization.

CIs	F_1-score (%)	Accuracy (%)	ROC-AUC[a] (%)
Lower confidence (2.5%)	9.7	7.22	5.57
Upper confidence (97.5%)	27.73	23.54	20.65

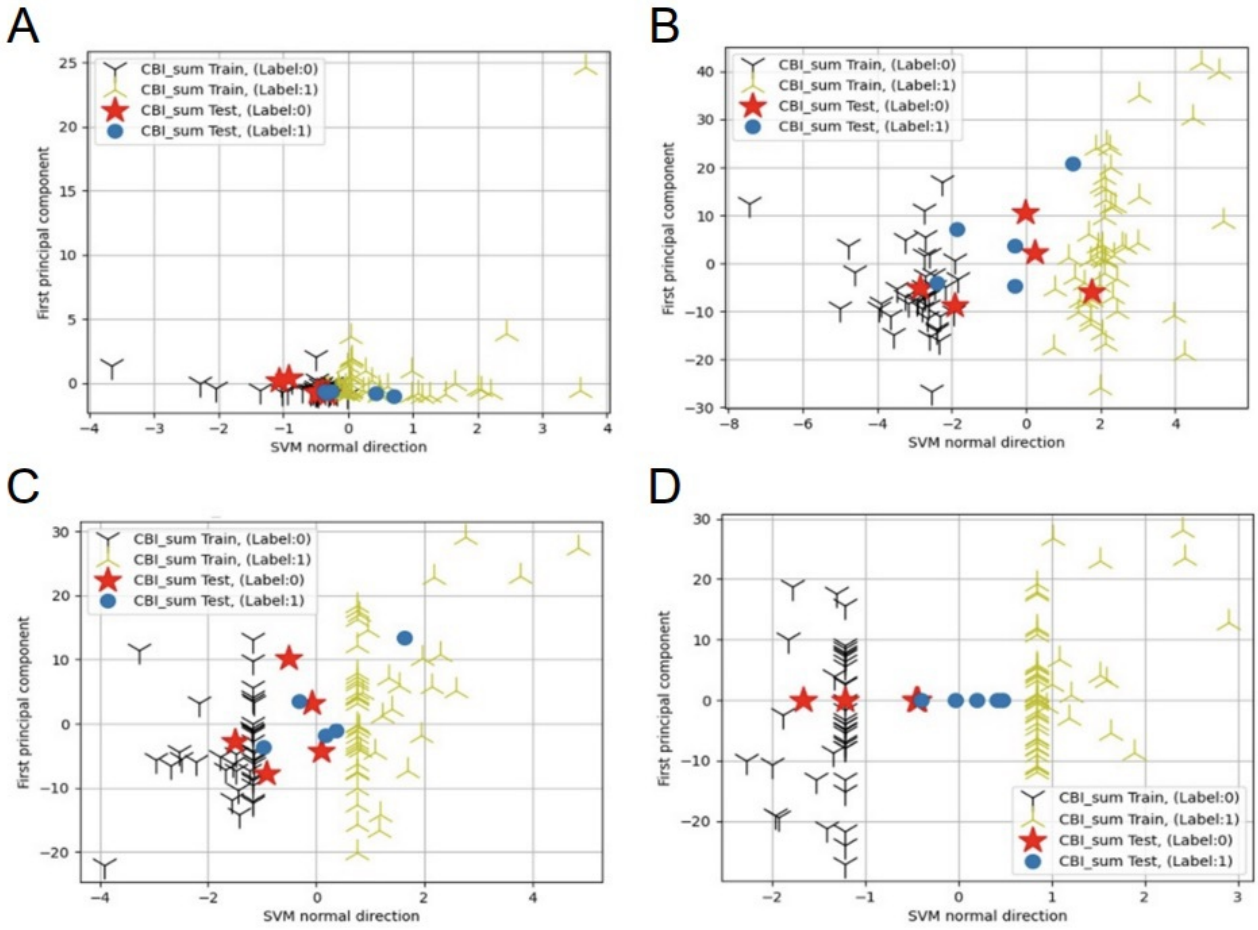
[a]ROC-AUC: receiver operating characteristic-area under the curve.

Similar results were observed with the other classifier models (SVM-sigmoid, SVM-RBF, and SVM-poly), underscoring the importance of processing acoustic features through orthogonalization in order to enhance classifier performance in predicting stress status.

Stress Status Classification Performance

The effectiveness of the best-performing SVM-linear model in classifying stress status in one of the testing sets of the 10-fold cross-validation is depicted in Figure 4. The SVM-linear model demonstrated only fair performance with regard to linguistic features alone (Figure 4A) or acoustic features alone (Figure 4B). Performance remained moderate even when combining features without processing the acoustic features through orthogonalization (Figure 4C). This indicates that proper feature processing, along with the fusion of linguistic and acoustic features in the SVM-linear model, provides strong predictive power for identifying individuals' stress status based on their speech.

Figure 4. Performance with regard to classifying the stress status of testing samples using the linear support vector machine (SVM-linear) model under different feature settings. (A) Linguistic features only, (B) acoustic features only, (C) combined features without orthogonalization, and (D) combined features with orthogonalization. "Label: 0" represents the low-stress group and "Label: 1" represents the high-stress group. SVM: support vector machine.



Effects of Small Datasets

As our dataset is small, the proposed operations (using PCA and orthogonalization procedure) may affect the model's performance. To verify this, we applied the SVM-linear model with double cross-validation 100 times with 100 different random seeds [39]. For each fold, we used the 3 evaluation measures: F_1-score, accuracy, and ROC-AUC. The means and SDs of these 100 evaluation measures were reported in Table 5. It can be observed that the performances with the orthogonalization process are still above 70% for the 3 metrics. It is much better than the one without orthogonalization. Table 6 reports TPRt (also known as sensitivity), false positive rate, false negative rate, and true negative rate (also known as specificity), further justifying the reliability of the SVM-linear model.

Table . Performance of the linear support vector machine (SVM-linear) model under different feature settings and processing with double cross-validation 100 times with 100 different random seeds.

Feature setting	F_1-score (SD), %	Accuracy (SD), %	ROC-AUC[a] (SD), %
Combined (linguistic+acoustic) with orthogonalization	74.89 (1.83)	71.90 (1.83)	76.83 (3.65)
Combined (linguistic+acoustic) without orthogonalization	59 (4.17)	57.98 (3.69)	61.51 (3.92)
Linguistic only	71.84 (3.1)	69.5 (3.24)	75.29 (3.68)
Acoustic only	57.67 (2)	55 (1)	60.01 (2)

[a]ROC-AUC: receiver operating characteristic-area under the curve.

Table . Performance of the linear support vector machine (SVM-linear) model under different feature settings and processing with double cross-validation 100 times with 100 different random seeds.

Feature setting	TPR[a] (SD), %	FPR[b] (SD), %	FNR[c] (SD), %	TNR[d] (SD), %
Combined (linguistic + acoustic) with orthogonalization	76.48 (2.52)	33.52 (3.72)	23.52 (2.52)	66.48 (3.72)
Combined (linguistic + acoustic) without orthogonalization	57.17 (4.69)	40.36 (4.83)	42.83 (4.69)	59.64 (4.83)
Linguistic only	71.83 (3.84)	33.21 (5.2)	28.17 (3.84)	66.79 (5.2)
Acoustic only	59.33 (1)	50 (2)	40.67 (2)	50 (1)

[a]TPR: true positive rate.

[b]FPR: false positive rate.

[c]FNR: false negative rate.

[d]TNR: true negative rate.

Discussion

This study introduced LASAP, a novel speech analytics machine learning program that, to our knowledge, is the first to successfully utilize a fusion analysis of linguistic and acoustic speech features to identify psychosocial stress among family caregivers in the Chinese community. Our results demonstrate that LASAP can effectively distinguish between individuals with high and low stress levels, particularly when using the SVM-linear classifier model, underscoring the significant potential of advanced speech analytics as an objective and scalable tool for psychosocial health assessment.

The robustness of the LASAP approach was evident, with 4 classifier models (SVM-linear, SVM-sigmoid, SVM-RBF, and SVM-poly) achieving ROC-AUC values greater than 75%. The SVM-sigmoid and SVM-linear models were the top 2 performers, with ROC-AUC values of 78.77% and 78.28%, respectively. While the SVM-sigmoid model yielded a slightly higher ROC-AUC value than that of the SVM-linear model, a deeper examination of other performance metrics reveals a more nuanced picture. The strong performance on additional metrics, particularly high F_1-score and accuracy, is crucial, as these indicate the model's precision and recall in identifying individuals under stress. The SVM-sigmoid model's lower F_1-score (71.67%) and accuracy (56%) suggest that it was biased toward correctly identifying the high-stress state, potentially at the expense of misclassifying low-stress individuals. In contrast, the SVM-linear model demonstrated a more balanced performance, with a superior F_1-score (75.27%) and accuracy (73%). In psychosocial health-screening applications, where the goal is to accurately identify those who need support and those who do not, this balanced performance is critical. Therefore, the SVM-linear model's consistent superiority across all 3 metrics establishes it as the most robust and reliable classifier for practical applications.

The strong performance of the LASAP with the SVM-linear model has significant implications for addressing the well-documented challenges in psychosocial condition management. With 75% of individuals in need not receiving adequate intervention [3] and the WHO reporting that only 25% of the member states have integrated mental health services into primary health care [40], the need for scalable solutions is urgent. However, traditional psychosocial health assessments are the major bottleneck as they are time-consuming, require specialist administrators, can be subjective, and are vulnerable to clients' self-report bias [8,9]. By providing an objective, automated, and effective alternative, LASAP directly targets these limitations. Its ability to analyze speech from a brief, nonsensitive interview could make it a practical tool for widespread screening, helping to identify at-risk individuals who can then be referred for further support.

The efficiency gains offered by LASAP are substantial. Our data collection based on 30-minute interviews using 12 general questions (Table S1 in Multimedia Appendix 1) is considerably shorter than the 1 to 2 hours often required for conventional assessments utilizing multiple instruments. This efficiency, coupled with its automated and objective nature, positions LASAP as a tool that could significantly enhance the accessibility of psychosocial screening. Its use of nonsensitive questions is a key strength as it mitigates the response bias, which is a common limitation of traditional self-reports, by allowing participants to express themselves naturally [8]. For a vulnerable population, such as family caregivers, this provides a less intrusive and more accurate assessment of their psychosocial well-being.

Another key contribution of this study is the comparative analysis using linguistic features, acoustic features, and their combination in the assessment of stress. Previous research has often focused on either linguistic or acoustic features in isolation. In our study, the combination of these features yielded significantly improved results, with the SVM-linear model achieving an ROC-AUC value of 78.28% when both types of features were analyzed together. In contrast, the use of linguistic features alone resulted in an ROC-AUC value of 76.68%, while acoustic features alone achieved an ROC-AUC value of only 60.92%. Similar improvements were observed in the high-performing models, including SVM-sigmoid, SVM-RBF, and SVM-poly. These findings clearly demonstrate that the fusion of linguistic and acoustic features enhances the model's predictive power, supporting the hypothesis that a multifaceted

approach to speech analytics can lead to more accurate assessments of psychosocial stress. This not only confirms the value of feature fusion but also suggests that future research should explore combined feature sets more extensively, which may advance model robustness and enhance applications in real-world scenarios.

Furthermore, our study indicated that the proper processing of acoustic features is pivotal to the effectiveness of the LASAP. Our study implemented an orthogonalization procedure to decorrelate acoustic features from linguistic features before combining them for analysis. This step is critical in reducing the risk of overfitting, which can occur when redundant information is present in the data. Emotional intensity conveyed by both linguistic and acoustic features can create a misleadingly strong signal if not managed properly. The results indicate the necessity of this orthogonalization process for decorrelation. When the SVM-linear model was applied to combined features without decorrelation, the ROC-AUC value dropped dramatically to 57.22%, a stark contrast to the optimal ROC-AUC value of 78.28% achieved with orthogonalized features. Similar results were observed in the SVM-sigmoid, SVM-RBF, and SVM-poly models. This indicates that the proper processing of acoustic features can greatly reduce overfitting and improve the accuracy and reliability of stress status classification. These findings point to a broader significance in the application of machine learning techniques in our field, suggesting that enhanced feature processing could be vital for other models and datasets to bolster model performance.

The implications of this study extend beyond the immediate findings. The successful application of the LASAP in identifying stress among family caregivers opens avenues for broader applications in various populations experiencing psychosocial stressors. Future research should explore the applicability of this model in diverse settings, including psychosocial health screenings in workplaces, educational institutions, and community health initiatives. Moreover, the insights gained from this study can inform the development of more sophisticated automated systems that integrate multiple features and ensure proper processing. As psychosocial conditions continue to rise globally, the demand for accessible, efficient, and accurate assessment tools becomes increasingly urgent. The LASAP exemplifies how the integration and proper processing of features can provide accurate assessments, facilitating timely interventions and support for individuals in need.

While the results are promising, this study has limitations. The sample size of 100 family caregivers, though adequate for preliminary findings, may not fully capture the diversity of experiences among different caregiver populations. Future studies should aim for larger, more diverse samples to validate the findings and enhance generalizability. Additionally, exploring the influence of demographic factors, such as age, gender, and cultural background, on speech characteristics could provide deeper insights into the psychosocial stress assessment [41]. Moreover, while our focus was on stress identification, future research could also investigate the potential of the LASAP in assessing other psychosocial conditions, such as anxiety and depression, through similar fusion analyses. The model's adaptability could pave the way for a comprehensive suite of tools addressing various aspects of psychosocial health.

This study highlights the significant potential of integrating linguistic and acoustic features for the automated assessment of psychosocial stress. The excellent performance of the SVM-linear model reinforces the importance of using combined features and proper processing techniques, such as orthogonalization, to enhance predictive accuracy. As we move toward an era of digital health solutions, the findings from the LASAP can serve as a foundation for developing innovative tools that improve mental health assessments and interventions, ultimately contributing to better psychosocial outcomes for individuals across various contexts.

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Data Availability

The datasets analyzed during this study are not publicly available, but they are available from the corresponding author upon reasonable request.

Authors' Contributions

Conceptualization: AMYC, MKPS
Data curation: AMYC, BSYL, MKPS, JTYT, AT
Formal analysis: MKPS, BSYL, JNLC
Investigation: AMYC, MKPS, JTYT, BSYL, JNLC, AT
Writing - original draft: AMYC, JTYT, BSYL, JNLC

Writing - review and editing: MKPS, AT
All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Illustration of the orthogonalization procedure, interview questions, caregiver stress-indicating words and topics related to Walsh's family resilience theory, description of acoustic features, hyperparameters of different machine learning classifiers, and implementation details of the proposed algorithm.
[DOCX File, 148 KB - biomedeng_v11i1e91138_app1.docx]

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Abbreviations

ASAP: Automatic Speech Analytic Program
CBI: Caregiver Burden Inventory
COMPARE: Computational Paralinguistics Challenge
LASAP: Linguistic and Acoustic Speech Analytics Program
LLD: low-level descriptor
PCA: principal component analysis
ROC-AUC: receiver operating characteristic-area under the curve
SVM: support vector machine

SVM-linear: linear support vector machine
SVM-poly: polynomial support vector machine
SVM-RBF: radial basis function support vector machine
SVM-sigmoid: sigmoid kernel support vector machine
TPR: true positive rate
WHO: World Health Organization

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Age-Related Differences in Joint Kinematics and Spatiotemporal Parameters During Ramp Walking and Level Walking: Cross-Sectional Study

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Abstract

Background: Gait function is essential for mobility and independence in older adults. Although age-related gait decline on level walking has been studied extensively, there is less information on how aging affects gait during ramp walking, despite its relevance in daily life. Different biomechanical strategies are used during ramp ascent and descent; however, detailed joint kinematics remain unclear, particularly under real-world conditions.

Objective: This study aims to investigate age-related differences in lower-limb joint angles and spatiotemporal parameters between level and ramp walking.

Methods: Gait was assessed in 20 young (mean 31.3, SD 8.9 y) and 20 older (mean 64.2, SD 0.8 y) healthy adults using a markerless motion-capture system (Theia3D) in a living laboratory setting. Participants completed gait trials during level walking and on a 7° ramp (ascent and descent). Between-group comparisons of spatiotemporal parameters were performed using independent 2-tailed *t* tests, while joint angle data were analyzed using a linear mixed model with walking velocity as a covariate. Estimated marginal means were compared across age groups within each walking condition, and all *P* values were adjusted using the false discovery rate method. Effect sizes were calculated using Cohen *d* to examine whether between-group differences were more pronounced during ramp walking compared to level walking.

Results: Ramp walking revealed multijoint kinematic alterations, while level walking showed limited differences (hip flexion and knee extension angles only). During ramp ascent, significant increases in knee flexion angle and reductions in ankle plantarflexion angle were observed. During ramp descent, multijoint changes were evident, including increased hip flexion and reduced knee extension and ankle plantarflexion angles. Effect sizes were particularly large during ramp walking (eg, knee flexion during ascent: $|d|$=2.37; knee extension during descent: $|d|$=1.87), while level walking showed large effect sizes for several parameters (eg, knee $MaxExt_{Stance}$: $|d|$=1.18; hip $MaxFlex_{Stance}$: $|d|$=1.17) despite reaching statistical significance for only a few parameters.

Conclusions: In this cross-sectional sample, age-group differences in joint kinematics were more pronounced during ramp walking than during level walking, even after adjusting for walking velocity. This suggests that ramp walking may be a more sensitive task for detecting age-related adaptations compared to level walking. Markerless motion capture enables practical assessment in real-world settings. However, longitudinal studies are needed to determine whether these patterns predict functional decline.

Trial Registration: UMIN Clinical Trials Registry UMIN000049283; https://center6.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000056122 and UMIN000049284; https://center6.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000056126

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KEYWORDS

gait analysis; aging; ramp walking; markerless motion capture; living laboratory

Introduction

Gait is fundamental to human mobility and independence. It is a daily activity performed without conscious effort. Despite this apparent ease, walking is a complex motor task that requires sophisticated coordination among the nervous, musculoskeletal, and cardiorespiratory systems to precisely control gait parameters (eg, walking velocity, cadence, and step length) throughout each gait cycle [1]. Consequently, gait function declines when these physiological systems are compromised [1]. Aging is one of the primary contributors; as the global population ages [2], more older adults experience declines in gait function [3]. This deterioration restricts essential activities of daily living—such as level walking, ramp walking, and stair climbing—and reduces physical activity, creating a negative cycle that accelerates motor function decline. Understanding the mechanisms underlying age-related gait decline is crucial for preventing this cycle and supporting older adults' independence.

Extensive research has examined age-related gait decline, especially during level walking. Compared to young adults, older adults exhibit shorter stride lengths, reduced gait velocity [4], greater gait variability [5,6], prolonged double support time [7,8], and reduced ankle range of motion (RoM) [9]. Meta-analyses confirmed that ankle plantarflexion limitations were particularly pronounced in older populations (≥65 y), with reductions of approximately 5° compared to young adults [10]. These variations are attributed to age-related decline in neuromuscular function [11,12], including alterations in joint power generation and redistribution strategies [8,13]. Additionally, older adults consume 20% to 30% more physiological metabolic energy during walking than young adults [7], suggesting lower gait energy efficiency.

Unlike level walking, ramp walking involves distinct movement strategies [14,15], suggesting that age-related gait deterioration may vary by environment. Despite its importance in daily life, studies on age-related changes during ramp ascent and descent remain limited. Existing evidence suggests that older adults exhibit shorter stride length and reduced maximum ankle plantarflexion angle during ramp ascent [16] and reduced velocity, shorter stride length, and increased cadence during ramp descent on a 20% slope [17]. However, the underlying biomechanical mechanisms, such as joint kinematics, remain unclear. Notably, the reported reduction in ankle plantarflexion during ramp ascent [16] was based on treadmill assessment, which may not accurately reflect real-world conditions. Treadmill walking patterns have been shown to differ from natural gait on both level surfaces [18,19] and inclines [20]. This knowledge gap highlights the need for assessing ramp walking kinematics in settings that closely approximate real-world conditions.

To address this gap, our center established a "living laboratory" [21] to evaluate the activities of daily living of older adults under conditions that closely mimic real-world environments. The living laboratory features an indoor space and a separate outdoor recreational space simulating daily living environments, both equipped with a markerless motion-capture system, Theia3D (ver2021.2.0.1675, Theia Markerless Inc). Theia3D's accuracy is comparable to conventional marker–based systems [22,23], with measurement errors below 5° [24], enabling natural gait assessments without special clothing or physical markers. This level of accuracy is sufficient for clinical applications [25]. Consequently, gait measurements performed in the living laboratory environment can provide accurate and reproducible data that reflect natural walking behavior [24].

This study assessed sagittal-plane lower-extremity joint angles in young and older adults across three living laboratory walking conditions: level walking, ramp ascent, and ramp descent. We aimed to test the hypothesis that age-related lower-extremity joint angle limitations are more pronounced in ramp walking than in level walking. We compared joint kinematics and calculated effect sizes between age groups in all 3 conditions to evaluate age-related differences in joint angle parameters during ramp walking compared to level walking.

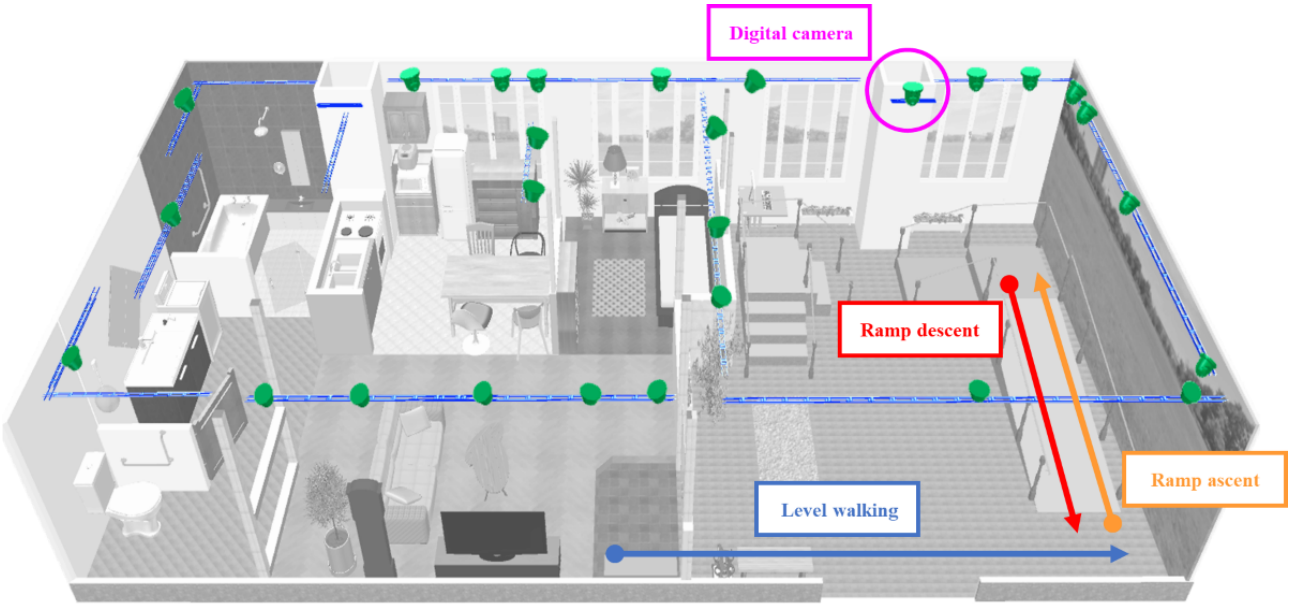
Understanding these age-related lower-extremity kinematic adaptations may inform targeted interventions for preserving mobility and maintaining physical independence in older adults. Ultimately, this knowledge could improve the quality of life in aging populations.

Methods

Measurement Environment

This study was conducted in a living laboratory environment comprising outdoor and indoor spaces. Gait assessments were performed on level ground, and a ramp was used in the outdoor area. The level walking path was 7 m long, whereas the ramp was 3.25 m long, with a 7° incline and handrails on both sides (Figure 1). The slope angle used in this study was designed based on the maximum gradient specified in Japan's Building Standards Act [26], which is commonly encountered in barrier-free public and residential environments. This design ensures that the experimental conditions reflect real-world walking scenarios.

Figure 1. Experimental setup of the living laboratory and walkways for level walking and ramp walking measurements. Twenty-seven digital cameras for motion analysis are mounted on the ceiling and arranged to cover almost the entire area of the room (indicated by green objects).



Participants

A total of 40 healthy participants were recruited, including 20 young adults (15 male adults, 5 female adults; mean age 31.3, SD 8.9 y; mean height 1.68, SD 0.09 m; mean weight 63.5, SD 12.4 kg) and 20 older adults (11 male adults, 9 female adults; mean age 64.2, SD 0.8 y; mean height 1.65, SD 0.08 m; mean weight 63.7, SD 10.5 kg). The younger adults were members of the rehabilitation staff at the National Center for Geriatrics and Gerontology. In contrast, the older adults were enrolled in the Silver Human Resources Center, a work-support organization in Japan. Participants were asked to wear comfortable clothing suitable for physical activity to the testing site. Participants with any neurological or musculoskeletal conditions affecting gait were excluded.

Data Capture

Motion data were collected using 27 synchronized cameras (DSC-RX0M2; Sony Corporation) at a sampling rate of 60 Hz. The participants completed 5 trials each for 3 walking tasks performed in the following order: level walking, ramp ascent, and ramp descent (Figure 1). For each walking condition, the participants were positioned at designated starting points. The researcher confirmed that the participants were ready before signaling them to begin walking with the right foot in all trials. Measurements were stopped once the participants reached the designated end point and came to a complete stop. The participants were instructed to start walking at a self-selected speed and to refrain from using the handrails during the ramp task.

Data Analysis

Video data were processed using Theia3D, which uses inverse kinematics and a 2-degrees-of-freedom knee model to estimate 3D body segment postures. A low-pass filter based on the generalized cross-validatory spline with a cutoff frequency of 6 Hz was applied. The calculated data were then exported to Visual3D (HAS-Motion) for spatiotemporal parameter analysis and kinematic analysis.

Initial contact (IC) and toe-off events were identified using the algorithm proposed by Zeni et al [27]. Visual confirmation and manual correction of misclassified events were performed using the 3D motion animation.

For level walking, data analysis began with the third step after the initial movement from a standing position and ended 3 steps before stopping. For ramp walking, data analysis began with the second step after the initial movement from a standing position and ended one step before stopping.

As previous studies have demonstrated that foot strike patterns influence joint kinematics [28], participants' foot strike patterns were classified as heel strike or forefoot strike.

Spatiotemporal parameters, including cadence, velocity, and step length, were calculated for the analyzed gait cycles. These parameters were averaged across all measured trials within each walking condition, and the mean values were used as representative values for each participant.

Movements in the frontal and horizontal planes were excluded from the analysis to focus on sagittal plane joint angles. Sagittal angles of the bilateral hip, knee, and ankle joints were calculated as relative angles between the proximal and distal segments in their respective joint coordinate systems. For each trial, joint angles of the right and left limbs were time-normalized to represent 100% of the gait cycle, with 0% corresponding to IC and 100% to the next ipsilateral IC, and then averaged across limbs. The resulting waveforms were further averaged across all measured trials within each walking condition to obtain a representative waveform for each participant. Representative kinematic values were extracted based on the sagittal plane joint angle analysis conducted by Riazati et al [29] (Table 1).

Table . Definitions of representative values derived from time-series waveforms of sagittal-plane lower limb joint angles (hip, knee, and ankle).

Gait event	Description
ST1[a]	Stance phase 1, ipsilateral initial contact to mid-stance, representing the first half of the stance phase
ST2	Stance phase 2, mid-stance to ipsilateral toe-off, representing the second half of the stance phase
ST or SW[b]	Transition from stance-to-swing phase
RoM[c]	The entire range of motion over the full gait cycle, presented for hip, knee, and ankle joints in sagittal planes
MaxFlexStance	Maximum flexion angle (sagittal plane) achieved by the hip or knee joint during the stance phase
MaxFlexSwing	Maximum flexion angle (sagittal plane) achieved by the hip or knee joint during the swing phase
MaxFlexST1	Maximum flexion angle (sagittal plane) achieved by the knee joint during stance phase 1
MaxExtStance	Maximum extension angle (sagittal plane) achieved by the hip or knee joint during the stance phase
MaxDorsiflexionST2	Maximum dorsiflexion angle (sagittal plane) achieved by the ankle joint during the stance phase 2
MaxPlantarflexionST/SW	Maximum plantarflexion angle (sagittal plane) of the ankle joint at stance-to-swing transition
AnkleInitialContact	Ankle joint angle (sagittal plane) at initial contact

[a]ST: stance.

[b]SW: swing.

[c]RoM: range of motion.

Statistical Analysis

For spatiotemporal parameters, data normality was assessed using the Shapiro-Wilk test, which confirmed normality for all parameters (P>.05). Mean values and SDs were calculated for cadence, velocity, and step length for each walking condition (level walking, ramp ascent, and ramp descent). Between-group comparisons were performed using independent 2-sample independent 2-tailed t tests. The false discovery rate (FDR) method was applied for multiple comparison correction. Effect sizes were calculated using Cohen d and interpreted as follows: negligible ($|d|$<0.2), small ($|d|$<0.5), medium ($|d|$<0.8), and large (0.8≤$|d|$). The purpose of calculating effect sizes was to determine whether between-group differences were more pronounced during ramp ascent or ramp descent walking compared to level walking.

For joint angle data, representative values (eg, RoM, $MaxFlex_{Stance}$, $MaxFlex_{Swing}$) were extracted for the hip, knee, and ankle joints for each participant and walking condition, resulting in a total of 36 joint angle parameters for analysis. A linear mixed model (LMM) was used to adjust for the confounding effect of walking velocity, which differed significantly between age groups and is known to influence joint kinematics [30]. The model was configured with joint angle as the dependent variable, walking velocity as a covariate, age group (young adults vs older adults) as a between-participant factor, and walking condition (level walking, ramp ascent, ramp descent) as a within-participant factor. Model fitting was performed using the lme4 package (version 1.1.37) [31], with participant included as a random intercept to account for repeated measures within individuals. Representative kinematic values from each participant and walking condition were included as observations.

The normality of residuals from the LMM was assessed using the Shapiro-Wilk test. The results indicated a deviation from normality for the maximum ankle plantarflexion angle (P=.04). However, the visual inspection of the Q-Q plots revealed no extreme outliers, suggesting that the deviation was minor. Given these findings and the robustness of LMMs to minor normality violations [32], the maximum ankle plantarflexion angle was considered to meet the normality assumption.

Main effects and interactions were tested using type 3 analysis of variance with Satterthwaite approximation for degrees of freedom, implemented via the lmerTest package (version 3.1.3) [33]. For joint angle parameters showing significant interactions, simple main effects were evaluated using the emmeans package (version 1.11.2 - 8) [34], which calculated estimated marginal means and pairwise comparisons between age groups within each walking condition. The FDR method was applied to all P values obtained from the simple main effects tests to correct for multiple comparisons. Effect sizes (Cohen d) were calculated as the difference in estimated marginal means divided by the residual standard deviation from the LMM and interpreted using the same criteria as those for the spatiotemporal parameters.

All statistical analyses were performed using R (version 4.4.2) and RStudio (version 2025.09.2 Build 418), with a significance level set at P<.05.

Ethical Considerations

The study protocols were approved by the Ethics and Conflict of Interest Committee of the National Center for Geriatrics and Gerontology (approval numbers 1636 and 1637). Written informed consent was obtained from all participants prior to their inclusion in the study. All participants were assigned unique identification codes, and personal identifiers were removed from the dataset to ensure anonymity. The younger adult participants (rehabilitation staff) did not receive compensation. The older adult participants, recruited through the Silver Human Resources Center, received monetary compensation.

Results

Foot-Strike Pattern and Spatiotemporal Parameters

An analysis of foot-strike patterns revealed that all the lower limbs analyzed showed a heel-strike pattern. Table 2 presents the results of the spatiotemporal parameters, including the cadence (steps/min), velocity (m/s), and step length (m).

Table . Summary of spatiotemporal gait parameters (cadence [steps/min], velocity [m/s], and step length [m]) during level walking and ramp ascent or descent.

Task and spatiotemporal parameters	Young adults, mean (SD)	Older adults, mean (SD)	*P* value[a]	Effect sizes[b]	Effect size magnitude
Cadence (step/min)					
Level walking	114.14 (5.43)	114.13 (8.30)	>.99	0.001	Negligible
Ramp ascent	104.16 (5.70)	102.04 (7.74)	.40	0.312	Small
Ramp descent	112.60 (5.35)	112.04 (10.60)	.60	0.067	Negligible
Velocity (m/s)					
Level walking	1.39 (0.13)	1.28 (0.18)	.06	0.684	Medium
Ramp ascent	1.24 (0.10)	1.08 (0.10)	*<.001*	1.614	Large
Ramp descent	1.27 (0.15)	1.11 (0.16)	.004	1.055	Large
Step length (m)					
Level walking	0.73 (0.06)	0.67 (0.07)	*.01*	0.967	Large
Ramp ascent	0.72 (0.05)	0.64 (0.05)	*.003*	1.554	Large
Ramp descent	0.67 (0.07)	0.59 (0.07)	*.003*	1.077	Large

[a]Values in italics indicate statistically significant differences at $P<.05$.

[b]Effect sizes were calculated using Cohen *d* and interpreted as negligible ($|d|<0.2$), small ($|d|<0.5$), medium ($|d|<0.8$), or large ($0.8 \leq |d|$).

Differences were observed in the velocity and step length, with the older adults group exhibiting a lower velocity and smaller step length than the young adults group; however, there were no differences in cadence. Specifically, the mean walking velocity was numerically lower in the older group than in the young group during level walking (young adults: 1.39, SD 0.13 m/s vs older adults: 1.28, SD 0.18 m/s; $P=.06$), though this difference did not reach statistical significance. The velocity difference was significant during ramp ascent (young adults: 1.24, SD 0.10 m/s vs older adults: 1.08, SD 0.10 m/s; $P<.001$) and ramp descent (young adults: 1.27, SD 0.15 m/s vs older adults: 1.11, SD 0.16 m/s; $P=.004$).

Although no significant difference in height was observed between the young adult and older adult groups (independent 2-tailed *t* test; $P=.25$), the mean step length showed significant differences under all conditions, with older adults exhibiting shorter step length than young adults: level walking (young adults: 0.73, SD 0.06 m vs older adults: 0.67, SD 0.07 m; $P=.01$), ramp ascent (young adults: 0.72, SD 0.05 m vs older adults: 0.64, SD 0.05 m; $P=.003$), and ramp descent (young adults: 0.67, SD 0.07 m vs older adults: 0.59, SD 0.07 m; $P=.003$).

Typical Value of Joint Angle

Figure 2 shows the time-series waveforms of the hip, knee, and ankle joint angles throughout the gait cycle for both age groups. Table 3 summarizes the representative values derived from these waveforms.

During level walking, significant differences were observed between age groups for 2 parameters: hip $\text{MaxFlex}_{\text{Stance}}$ (young adults: 24.1° vs older adults: 26.7°; $P=.04$) and knee $\text{MaxExt}_{\text{Stance}}$ (young adults: 1.4° vs older adults: −1.5°; $P=.009$).

During ramp ascent, significant differences between age groups were observed for 4 parameters: hip $\text{MaxExt}_{\text{Stance}}$ (young adults: 17.3° vs older adults: 20.4°; $P=.04$), knee $\text{MaxFlex}_{\text{ST1}}$ (young adults: 25.0° vs older adults: 33.4°; $P<.001$), ankle RoM (young adults: 39.9° vs older adults: 35.8°; $P=.009$), and ankle $\text{MaxPlantarflexion}_{\text{ST/SW}}$ (young adults: 20.5° vs older adults: 15.4°; $P<.001$).

During ramp descent, significant differences between age groups were observed for 5 parameters: hip $\text{MaxFlex}_{\text{Stance}}$ (young adults: 21.9° vs older adults: 25.7°; $P=.008$), hip $\text{MaxFlex}_{\text{Swing}}$ (young adults: 24.8° vs older adults: 28.2°; $P=.018$), knee $\text{MaxFlex}_{\text{ST1}}$ (young adults: 23.5° vs older adults: 28.7°; $P=.018$), knee

$MaxExt_{Stance}$ (young adults: 0.5° vs older adults: −4.1°; P<.001), and ankle $MaxPlantarflexion_{ST/SW}$ (young adults: 13.8° vs older adults: 9.9°; P=.012).

Regarding effect sizes, large effect sizes were observed during level walking for hip $MaxFlex_{Stance}$ (|d|=1.17), hip $MaxFlex_{Swing}$ (|d|=1.16), knee RoM (|d|=0.80), knee MaxFlexST1 (|d|=1.00), knee $MaxExt_{Stance}$ (|d|=1.18), ankle RoM (|d|=0.86), and ankle $MaxPlantarflexion_{ST/SW}$ (|d|=0.83). A small effect size was observed for knee $MaxFlex_{Swing}$ (|d|=0.22). Negligible effect sizes were observed for hip $MaxExt_{Stance}$ (|d|=0.02) and ankle $MaxDorsiflexion_{ST2}$ (|d|=0.00).

For ramp ascent, large effect sizes were observed for hip $MaxExt_{Stance}$ (|d|=1.36), knee RoM (|d|=0.82), knee $MaxFlex_{ST1}$ (|d|=2.37), knee $MaxFlex_{Swing}$ (|d|=1.73), ankle RoM (|d|=1.91), and ankle $MaxPlantarflexion_{ST/SW}$ (|d|=2.35). A medium effect size was observed for hip $MaxFlex_{Stance}$ (|d|=0.50), and small effect sizes were observed for hip $MaxFlex_{Swing}$ (|d|=0.21), knee $MaxExt_{Stance}$ (|d|=0.49), and ankle $MaxDorsiflexion_{ST2}$ (|d|=0.44).

For ramp descent, large effect sizes were observed for hip $MaxFlex_{Stance}$ (|d|=1.67), hip $MaxFlex_{Swing}$ (|d|=1.67), hip $MaxExt_{Stance}$ (|d|=1.02), knee $MaxFlex_{ST1}$ (|d|=1.46), knee $MaxFlex_{Swing}$ (|d|=1.38), knee $MaxExt_{Stance}$ (|d|=1.87), ankle RoM (|d|=0.88), ankle $MaxDorsiflexion_{ST2}$ (|d|=1.18), and ankle $MaxPlantarflexion_{ST/SW}$ (|d|=1.79). A medium effect size was observed for knee RoM (|d|=0.52).

Figure 2. Time-series waveforms of lower limb joint angles (hip, knee, and ankle) in the sagittal plane during level walking and ramp ascent/descent. The waveforms are normalized with one gait cycle defined as 100%. The shaded areas around the waveforms represent the standard deviation.

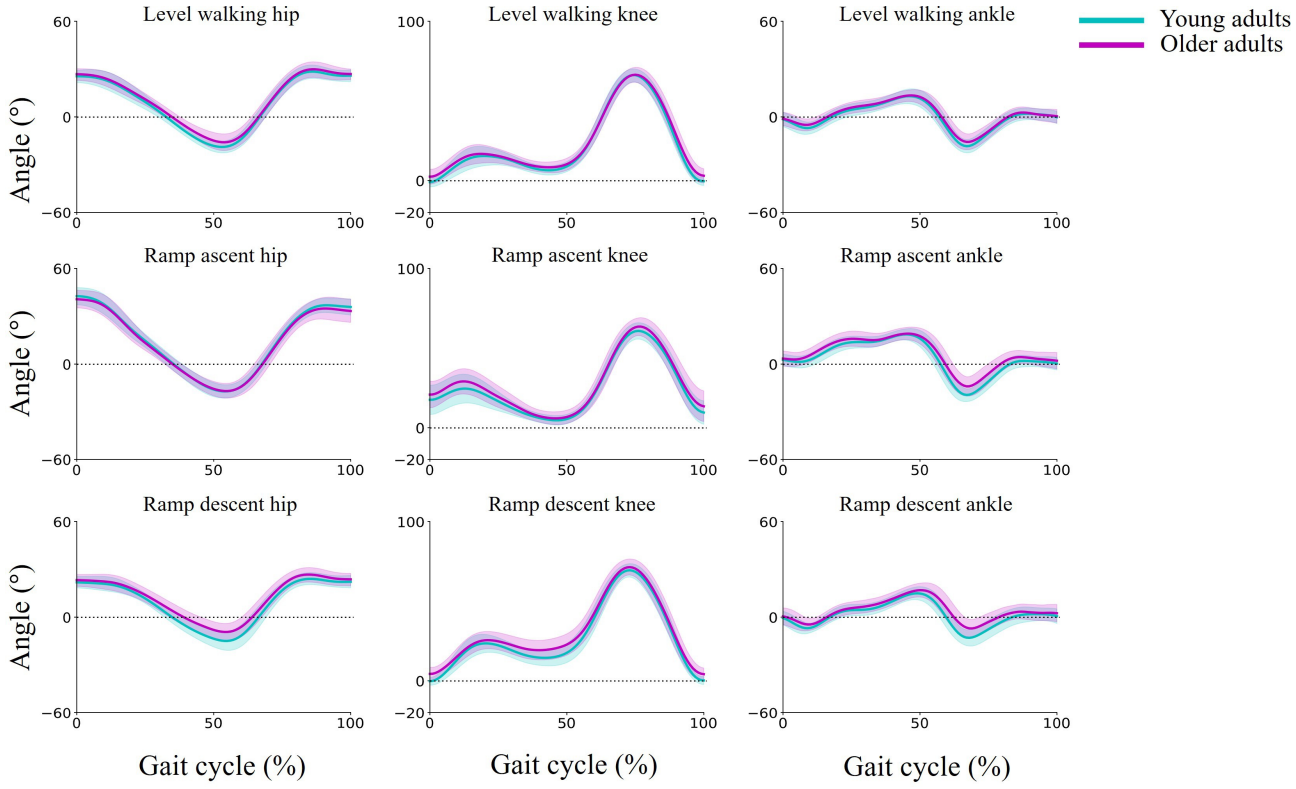


Table . Representative joint angle results (hip, knee, and ankle) in the sagittal plane during level walking and ramp ascent/descent.

Task and joint parameters	Young adults, EMMs[a]	Older adults, EMMs	*P* value[b]	Effect sizes[c]	Effect size magnitude
Level walking					
Hip (°)					
RoM[d]	44.5	47.2	n.s.[e]	—[f]	—
$MaxFlex_{Stance}$	24.1	26.7	*.04*	1.17	Large
$MaxFlex_{Swing}$	27.9	30.2	.09	1.16	Large
$MaxExt_{Stance}$	16.2	16.2	.995	0.02	Negligible
Knee (°)					
RoM	68.1	65.6	.19	0.80	Large
$MaxFlex_{ST1}$	13.7	17.3	.09	1.00	Large
$MaxFlex_{Swing}$	66.2	66.6	.81	0.22	Small
$MaxExt_{Stance}$	1.4	−1.5	*.009*	1.18	Large
Ankle (°)					
RoM	32.6	30.7	.19	0.86	Large
$MaxDorsiflexion_{ST2}$	14.1	14.1	.995	0.00	Negligible
$MaxPlantarflexion_{ST/SW}$	18.5	16.7	.19	0.83	Large
InitialContact	−2.0	−0.6	n.s.	—	—
Ramp ascent					
Hip (°)					
RoM	60.1	63.4	n.s.	—	—
$MaxFlex_{Stance}$	42.6	43.7	.39	0.50	Medium
$MaxFlex_{Swing}$	38.9	39.3	.79	0.21	Small
$MaxExt_{Stance}$	17.3	20.4	*.04*	1.36	Large
Knee (°)					
RoM	58.0	60.5	.19	0.82	Large
$MaxFlex_{ST1}$	25.0	33.4	*<.001*	2.37	Large
$MaxFlex_{Swing}$	61.0	64.3	.05	1.73	Large
$MaxExt_{Stance}$	−4.0	−5.2	.27	0.49	Small
Ankle (°)					
RoM	39.9	35.8	*.009*	1.91	Large
$MaxDorsiflexion_{ST2}$	19.3	20.0	.55	0.44	Small
$MaxPlantarflexion_{ST/SW}$	20.5	15.4	*<.001*	2.35	Large
InitialContact	1.3	3.8	n.s.	—	—
Ramp descent					
Hip (°)					
RoM	39.6	41.2	n.s.	—	—
$MaxFlex_{Stance}$	21.9	25.7	*.008*	1.67	Large
$MaxFlex_{Swing}$	24.8	28.2	*.02*	1.67	Large

Task and joint parameters	Young adults, EMMs[a]	Older adults, EMMs	*P* value[b]	Effect sizes[c]	Effect size magnitude
$MaxExt_{Stance}$	14.8	12.5	.11	1.02	Large
Knee (°)					
RoM	71.0	69.4	.39	0.52	Medium
$MaxFlex_{ST1}$	23.5	28.7	*.02*	1.46	Large
$MaxFlex_{Swing}$	69.9	72.6	.11	1.38	Large
$MaxExt_{Stance}$	0.5	−4.1	<.001	1.87	Large
Ankle (°)					
RoM	29.2	27.3	.19	0.88	Large
$MaxDorsiflexion_{ST2}$	15.3	17.4	*.11*	1.18	Large
$MaxPlantarflexion_{ST/SW}$	13.8	9.9	.01	1.79	Large
InitialContact	−0.3	2.2	n.s.	—	—

[a]EMM: estimated marginal mean.

[b]Values in italics indicate statistically significant differences at $P<.05$.

[c]Effect sizes are reported as Cohen *d* and interpreted as negligible ($|d|<0.2$), small ($0.2 \le |d|<0.5$), medium ($0.5 \le |d|<0.8$), or large ($0.8 \le |d|$).

[d]RoM: range of motion.

[e]n.s.: For parameters with no significant interaction (age group×task condition), simple main effects were not evaluated.

[f]Effect sizes were not calculated,

Discussion

Principal Findings

This study demonstrated that, after statistically adjusting for walking velocity using the LMM, ramp walking showed larger age-group differences in lower limb joint kinematics compared to level walking. While level walking showed large effect sizes for several parameters ($|d|$=0.80 - 1.18), only 2 parameters demonstrated statistical significance after adjusting for multiple comparisons using the FDR. In contrast, ramp conditions revealed larger effect sizes with high statistical significance. During ramp ascent, 4 parameters showed significant differences with large effect sizes ($|d|$=1.36 - 2.37), with the largest effects observed in knee flexion during early stance ($|d|$=2.37) and ankle plantarflexion ($|d|$=2.35). During ramp descent, 5 parameters showed significant differences with large effect sizes ($|d|$=1.46 - 1.87). The persistence of these large effect sizes after controlling for walking velocity differences indicates that the observed kinematic differences reflect age-related motor adaptations that emerge under challenging mobility conditions rather than simply being artifacts associated with different walking velocities. From these findings, it can be inferred that ramp walking has the potential to assess age-related kinematic adaptations that were less pronounced during level walking.

Physiological Mechanisms and Gait Strategy Adaptation

Age-related reductions in ankle plantarflexion angles during level walking have been consistently reported in previous studies examining older populations (≥65 y). A systematic review and meta-analysis by Pol et al [10] reported that older adults (≥65 y) showed significantly lower maximum ankle plantarflexion angles than young adults during level walking (weighted mean difference: −5.15°). In our study, although older adults tended to show lower maximum ankle plantarflexion angles than young adults during level walking (young adults: 18.5° vs older adults: 16.7°, $|d|$=0.83), this parameter did not reach significance, possibly reflecting the younger age of our cohort (mean: 64.2 y). While significant differences were observed in hip flexion and knee extension during stance, several parameters exhibited large effect sizes ($|d|$=0.80 - 1.18) without reaching significance, suggesting that level walking may not fully reveal age-related motor adaptations.

During ramp ascent walking, older adults showed coordinated multijoint adaptations. Significantly reduced ankle plantarflexion (young adults: 20.5° vs older adults: 15.4°, $|d|$=2.35) and ankle range of motion (young adults: 39.9° vs older adults: 35.8°, $|d|$=1.91) indicate compromised push-off capacity, consistent with age-related reductions in ankle power generation observed during level walking [8] and altered triceps surae muscle properties [35,36]. Hip extension during terminal stance significantly increased (young adults: 17.3° vs older adults: 20.4°, $|d|$=1.36), demonstrating compensatory reliance on proximal joints—a redistribution pattern where older adults shift from ankle-dominant to hip-dominant power generation [13], which becomes particularly pronounced during inclined walking [16].

In addition, knee flexion during early stance markedly increased (young adults: 25.0° vs older adults: 33.4°, $|d|$=2.37), the largest effect observed. This likely reflects reduced step length associated with diminished propulsive capacity, whereby ground contact occurs before full knee extension. This pattern may also

represent an adaptive strategy for stability during upward ambulation. These coordinated adaptations across the ankle, knee, and hip joints underscore the integrated nature of age-related motor modifications during inclined walking.

Furthermore, multijoint adaptations were also observed in older adults during ramp descent. During descent, significant increases in hip $MaxFlex_{Stance}$ (young adults: 21.9° vs older adults: 25.7°), hip $MaxFlex_{Swing}$ (young adults: 24.8° vs older adults: 28.2°), and knee $MaxFlex_{ST1}$ (young adults: 23.5° vs older adults: 28.7°) angles were observed, along with significant reductions in knee $MaxExt_{Stance}$ (young adults: 0.5° vs older adults: −4.1°) and ankle $MaxPlantarflexion_{ST/SW}$ (young adults: 13.8° vs older adults: 9.9°) angles.

These coordinated adaptations can be understood through 2 complementary biomechanical perspectives. First, from a neuromuscular control standpoint, ramp descent requires greater eccentric muscle contractions compared to level walking [37], particularly increasing knee and ankle joint angles [38]. Age-related decline in eccentric contraction capacity compromises postural control ability and increases fall risk [39]. The observed reductions in knee extension and ankle plantarflexion range of motion in older adults may therefore reflect declining eccentric control capacity during controlled descent.

Second, from a mechanical perspective, ramp descent walking intensifies the demand for gravitational impact absorption. Older adults commonly exhibit reduced ankle range of motion, particularly in plantarflexion [10], which alters propulsion, shock absorption, and kinetic patterns during gait [40]. During descent, the reduced knee extension and ankle plantarflexion angles observed in our older participants may indicate a diminished capacity to generate the negative joint torques required for effective shock absorption, potentially increasing mechanical loading on the lower limbs.

These coordinated joint restrictions likely represent adaptive strategies for maintaining postural stability during the challenging task of controlled lowering against gravity [14,15].

Clinical Significance

Most clinical gait evaluations rely on level walking as the standard assessment [7]. However, our findings reveal that ramp walking reveals age-related kinematic adaptations that level walking assessments largely miss. After controlling for walking velocity, the substantially larger differences during ramp conditions ($|d|$=1.46 - 2.37 vs 0.80 - 1.18) demonstrate systematic motor adaptations that may warrant clinical attention. These patterns—particularly the large effect sizes in ankle plantarflexion during ascent ($|d|$=2.35) and multijoint coordination during descent—represent specific targets for intervention development. Although our cross-sectional design cannot establish predictive relationships for functional decline, the magnitude and consistency of these differences suggest clinical relevance. Markerless motion capture technology makes such assessments practically feasible [41], enabling longitudinal validation studies to examine whether these patterns predict subsequent mobility decline or fall incidence over 5 - to 10-year follow-up periods. However, it should be noted that our research focused on identifying group-level kinematic differences and did not include diagnostic accuracy analyses. Further research, including longitudinal validation followed by diagnostic studies, is required before these kinematic patterns can be applied for clinical screening purposes.

Future Perspectives for Living Laboratory

The living laboratory's naturalistic outdoor setting with fixed inclines and markerless motion capture differs fundamentally from treadmill-based protocols used in previous ramp walking studies [16,18-20]. Treadmill constraints—predetermined speeds, continuous belt motion, and laboratory boundaries—may mask natural motor adaptations. Our environment allowed spontaneous ramp walking without such constraints, potentially capturing motor patterns that more closely resemble daily-life behavior compared to laboratory-constrained assessments. This ecological validity may partially explain the substantial age-related differences we observed. Furthermore, the living laboratory serves as a safe and iterative testing ground for emerging assistive technologies before clinical deployment. For example, the biomechanics-derived "Hug" transfer-assist robot was iteratively refined based on user feedback to better meet user requirements [42]. Similarly, the observed age-related limitations in ankle plantarflexion during ramp ascent could inform the development and testing of targeted interventions, such as mobility aids or training programs specifically designed to support inclined walking in older adults. Beyond these applications, the living laboratory may also be used to evaluate diverse technologies, including mobility aids, behavior-modifying sensor systems, and smart care robotics, and provide empirical data on their usability, safety, and functional effectiveness. Future research could leverage this infrastructure to incorporate more diverse real-world walking challenges, including stair negotiation, directional changes, and navigating uneven terrain or lateral slopes [43,44], thereby developing more comprehensive motor function assessment frameworks that better reflect the full spectrum of mobility demands faced by older adults in daily life. Through this infrastructure, the living laboratory facilitates the translation of research findings into practical interventions for supporting mobility in aging populations.

Research Limitations and Future Directions

This study has several limitations. First, only kinematic data were analyzed; kinetic data (eg, joint moments or forces) were not analyzed. Fully understanding gait kinematic strategies requires examining joint angles and mechanical power distribution. Prior studies show that older adults rely more on proximal joints [13,16], suggesting age-related motor strategy reorganization. Future studies that combine markerless motion capture with ground reaction force measurements and inverse dynamics via musculoskeletal modeling can offer deeper insights into age-related motor coordination changes [45,46].

Second, this study has limitations related to its design and sample characteristics. The participants were relatively young older adults (mean age 64.2, SD 0.8 y), limiting generalizability to frail or older populations. Additionally, sex distribution was unbalanced between groups (young: 15 male adults, 5 female adults; older: 11 male adults, 9 female adults), and given the

well-documented sex-related differences in gait biomechanics [47], this may have influenced the results. Furthermore, the cross-sectional design demonstrates age-group differences at a single time point but not longitudinal progression or predictive value for functional outcomes. Future studies should include broader age ranges and longitudinal designs to capture the full extent of age-related gait changes and determine whether these kinematic patterns predict subsequent falls or mobility impairment.

Third, cognitive and perceptual factors, such as fear of falling and attentional load, were not examined in this study despite their known impact on gait patterns. Research has demonstrated that cognitive-motor interactions, including dual-task performance, reveal age-related declines in attentional capacity and gait control during walking [48]. Future studies should incorporate assessments of these factors, including dual-task walking paradigms, to better understand the interplay between cognitive demands and motor control in older adults.

Fourth, while we statistically adjusted for walking velocity using linear mixed-effects models, several potential confounding factors (habitual physical activity, muscle strength, comorbidities, medications, footwear, and fear of falling) were not measured or controlled. Participants were recruited through a senior employment center, suggesting they were relatively healthy and physically active older adults. However, the lack of comprehensive health and physical function assessments limits our ability to determine whether the observed kinematic differences reflect aging per se or differences in health status and physical capabilities between volunteer groups. Future studies should include detailed assessments of these factors to better isolate age-related changes from health-related confounders.

Despite these limitations, this study demonstrates that ramp walking reveals greater age-related kinematic differences than level walking, even after controlling for walking velocity. Addressing these limitations in future research will advance the understanding of age-related gait mechanisms and their clinical relevance.

Conclusion

This study demonstrated that ramp walking is more effective than level walking in revealing age-related differences in gait. After adjusting for the confounding factor related to walking velocity, ramp conditions showed substantially greater differences, suggesting that ramp walking may help assess possible age-related motor decline more acutely than level walking. However, since ours was a cross-sectional study, we cannot establish predictive value. Longitudinal studies are needed to determine whether these patterns predict functional decline. This study provides cross-sectional evidence of age-group differences in gait kinematics during ramp walking and level walking, with larger between-group differences observed during ramp conditions in this sample.

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Data Availability

The datasets analyzed in this study are not publicly available but can be made available from the corresponding author upon reasonable request.

Authors' Contributions

KK and DS conceived the study. All authors designed the study protocol. TY, DS, MN, and SF performed the intervention and collected the data. DS, SF, and MN analyzed the data, prepared figures, interpreted the data, and wrote the paper. All authors revised the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

IC: initial contact
RoM: range of motion
LMM: linear mixed model
FDR: false discovery rate

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