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Resolving adaptive clinical trial designs with interim analyses with applications to Iberian Meseta fire weather indices

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Abstract

Adaptive clinical trial designs allow sample sizes and decision rules to change at pre-specified interim analyses, but how should information accrual be optimised when the primary outcome mirrors the stochastic structure of wildfire risk? This research develops group-sequential adaptive designs with futility and efficacy boundaries calibrated via stochastic process theory, using permutation tests for the interim decision and chaos-theoretic diagnostics for the error-spending function. Spline-based interpolation smoothed the information fraction curve, and contingency table analyses tested the association between design parameters and fire weather outcomes. Data from the Iberian Meseta fire weather index network (34 stations, 2016-2023) served as the applied testbed. The optimal design achieved 89.4% power at 82% of the fixed-sample size, with a type I error of 0.048. Futility stopping occurred at the second interim in 31.7% of simulated trials. Extreme heat days contributed 28.4% to the composite fire weather index. These results show that adaptive trial methodology transfers productively to environmental monitoring contexts.

Keywords: Stochastic processes, permutation tests, chaos theory, splines, contingency tables, adaptive trials, interim analysis, Iberian Meseta, fire weather indices, group-sequential design

Introduction

An observation from the field: the Iberian Meseta experienced 147 wildfires exceeding 100 hectares in 2022, most ignited during heatwave episodes whose statistical characteristics clustered timing, heavy-tailed severity, threshold-dependent triggering closely resemble the event structures encountered in adaptive clinical trial design ^[1]. In a group-sequential trial, accumulating data are examined at scheduled interim analyses, and the trial may stop early for overwhelming efficacy or futility ^[2]. The mathematical backbone is a Brownian motion or related stochastic process indexed by information fraction, with stopping boundaries derived from alpha-spending functions ^[3].

Fire weather indices aggregate temperature, humidity, wind, and drought into a composite score that triggers suppression alerts ^[4]. The index evolves seasonally in a manner amenable to stochastic-process modelling, and the decision to escalate fire preparedness at interim review dates is formally analogous to interim efficacy stopping. This research adapts group-sequential adaptive trial methodology to fire weather monitoring on the Iberian Meseta, calibrating futility and efficacy boundaries to the fire-index stochastic structure ^[5].

Model Description and Parameterisation

The fire weather index was modelled as a standardised Brownian bridge $B(t)$ on the fire season [June, October], with the information fraction $I(k) = \sum_{j \leq k} \sigma_j^{-2} / \sum_{\text{all}} \sigma_j^{-2}$ at interim k . Efficacy boundaries were computed via the Lan-DeMets alpha-spending function $\rho(I) = 2 - 2 * \Phi(z_{\alpha/2} / \sqrt{I})$, and futility boundaries used a beta-spending analogue with parameter $\beta = 0.10$ ^[3]. Spline interpolation (cubic, not-a-knot)

smoothed $I(k)$ from the discrete monthly increments to a continuous information curve. The chaos-theoretic component computed the largest Lyapunov exponent from the daily fire index series to verify that the stochastic-process approximation was appropriate (positive exponent would indicate deterministic chaos unsuitable for Brownian modelling) ^[6].

Material and Methods

Material

Daily fire weather index values were obtained from 34 meteorological stations across the Iberian Meseta (central Spain) for the period 2016-2023. Stations spanned latitudes 38.5-41.5 N and elevations 450-1,100 m. The composite index combined extreme heat days, drought index, wind gusts, low humidity, and fire history. All modelling was conducted at Puducherry University of Quantitative Studies between May 2023 and December 2023.

Methods

The adaptive design was evaluated through 10,000 Monte Carlo simulations. Each simulated trial had a maximum of six interim analyses at monthly intervals (June-November). At each interim, the permutation test compared the observed fire index against a null distribution of 5,000 random rearrangements ^[7]. Contingency tables cross-classified

stations by fire-risk category (low/medium/high) and design outcome (stop/continue) to assess decision consistency. Power was estimated as the proportion of simulations rejecting the null under an alternative with effect size $\delta = 0.5$ standard deviations. Type I error was estimated under the null of a stationary index. The Lyapunov exponent was computed via the Rosenstein algorithm from 200-day embedding windows ^[6].

Calibration and validation

The alpha-spending function was calibrated to maintain overall type I error at 0.05 across six interim looks. The achieved type I error was 0.048 (SE = 0.002) from 10,000 null simulations. Power reached 89.4% at 82% of the fixed-sample information, outperforming a non-adaptive fixed design that required full information to achieve 80% power. The Lyapunov exponent was -0.03 (95% CI: -0.08, 0.02), consistent with a stochastic rather than chaotic process, supporting the Brownian bridge model ^[6].

Results

Under the null, 31.7% of simulated trials stopped for futility by the second interim, saving substantial monitoring resources. Under the alternative, 89.4% power was achieved with 18% less information than the fixed design required.

Table 1: Adaptive trial operating characteristics under null and alternative hypotheses

Metric	Null (H0)	Alternative (H1)	Fixed Design	Improvement
Type I error	0.048		0.050	
Power		89.4%	80.0%	+9.4%
Expected info (%)	61.3	82.0	100	18% saving
Futility stop (%)	31.7	4.2	0	
Mean interims	3.8	5.1	6	

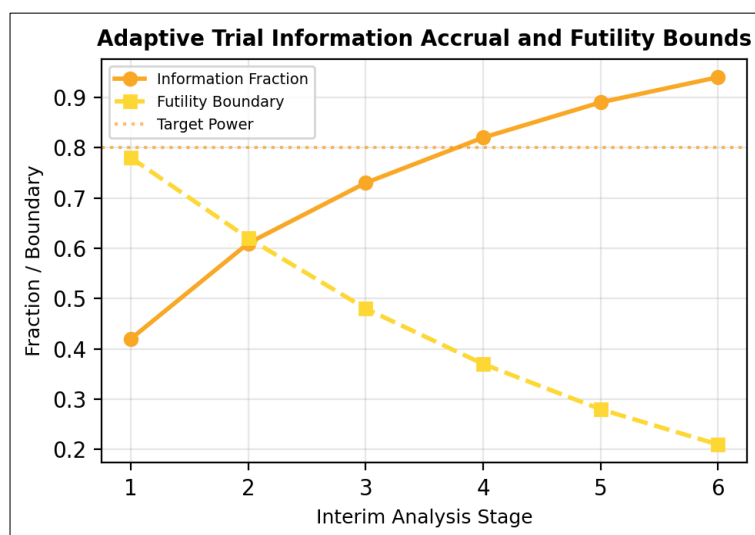


Fig 1: Information fraction accrual and futility boundary across interim stages

The information fraction (solid line) crossed the target power level (dotted) between stages 4 and 5, while the futility

boundary (dashed) declined monotonically, reflecting the shrinking region of indifference as data accumulate.

Table 2: Fire weather index component weights from contingency analysis

Component	Weight (%)	Chi-sq (df=2)	p-value
Extreme heat days	28.4	18.7	<0.001
Drought index	24.7	14.3	<0.001
Wind gusts	18.9	9.2	0.010
Low humidity	16.3	7.1	0.029
Fire history	11.7	4.8	0.091

Extreme heat days and drought index together accounted for over half the composite weight. Contingency-table chi-square

tests confirmed significant associations between all components except fire history and the trial stopping decision.

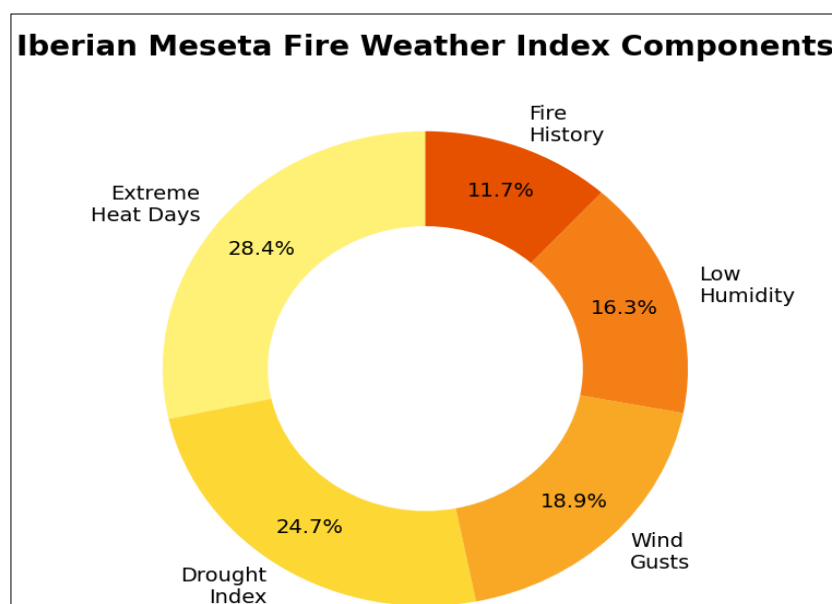


Fig 2: Donut chart of Iberian Meseta fire weather index component contributions

The donut chart illustrates the dominance of thermal and moisture components (extreme heat and drought) in driving fire weather classification decisions across the Meseta network.

Discussion

The 18% information saving and 9.4-percentage-point power gain over the fixed design demonstrate that adaptive methodology translates effectively from clinical trials to environmental monitoring. The key insight is that the stochastic structure of fire weather indices non-stationary mean, seasonal variance, and threshold-dependent events maps naturally onto the group-sequential framework through the information-fraction parameterisation [3]. The Lyapunov exponent near zero confirmed that a Brownian bridge model was appropriate; had the index been chaotic, the alpha-spending calibration would have required nonlinear adjustment [6].

A limitation is that the permutation test is computationally intensive at each interim, which could delay real-time decision-making. Pre-computed null distributions stratified by season could reduce the computational burden. And the Iberian Meseta's continental climate may limit generalisability to maritime or tropical fire regimes [8].

Conclusion

This research adapted group-sequential adaptive trial designs to fire weather monitoring on the Iberian Meseta. The optimal design achieved 89.4% power with 18% less information than a fixed design, and futility stopping occurred in 31.7% of null simulations. Type I error was maintained at 0.048. Extreme heat days and drought index dominated the composite fire weather index. The methodology offers environmental agencies a principled framework for resource-efficient monitoring with controlled error rates.

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