



Current Issues in Randomization in Sports Science Research: Limitations, Misconceptions, and Alternatives: Narrative Review

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ABSTRACT

Randomization is a central methodological component of experimental research because it supports causal inference, reduces selection bias, and improves the comparability of intervention groups. However, its implementation in sports science presents distinct methodological, ethical, and logistical challenges, including small and highly specialized samples, limited access to elite athletes, competition schedules, training constraints, intervention adherence, and difficulties in controlling contextual factors such as nutrition, recovery, and physical activity outside the study protocol. This narrative review examines the practical and methodological challenges associated with randomization in sports science and highlights common sources of bias, including inadequate allocation procedures, pseudo-randomization, poor adherence, and incomplete reporting. Random allocation procedures such as simple, block, stratified, and response-adaptive randomization remain valuable when appropriately aligned with the research question and study context, while randomized trial designs may include parallel-group, cluster-randomized, crossover, and stepped-wedge cluster-randomized structures. When conventional randomized trials are difficult to implement, quasi-experimental designs may provide alternative causal-inference strategies, whereas pragmatic trial frameworks and Bayesian inferential methods may be incorporated within randomized or non-randomized studies. Mendelian randomization, by contrast, is a distinct observational causal-inference method that uses genetic variants as instrumental variables and does not involve investigator-controlled allocation to experimental conditions. The review also considers digital tools such as randomizeR, RRApp, and OxMaR, which may support transparent allocation generation and reproducible reporting. Overall, this review emphasizes the need to balance methodological rigor with real-world feasibility in sport and exercise settings. By providing practical guidance on allocation strategies, study-design selection, bias mitigation, causal interpretation, and transparent reporting, this work aims to support researchers in designing studies that are ethically sound, contextually appropriate, and scientifically robust.

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Introduction

Randomization is a cornerstone of experimental design because it minimizes systematic allocation bias and, in expectation, distributes measured and unmeasured prognostic factors comparably across study groups, thereby strengthening causal inference and internal validity ([D. G. Altman & J. M. Bland, 1999](#); [Kang et al., 2008](#); [Mesquida et al., 2022](#)). Robust study designs are essential for generating reliable evidence that can inform practice, guide training interventions, and advance theoretical understanding. Among methodological tools, randomization stands out as a fundamental mechanism to control confounding factors and reduce bias, thereby enhancing the internal validity of research findings (["Randomization," 2023](#); [Shah & Vingan, 2023](#)).

Randomization strengthens causal inference by making treatment allocation independent of participant characteristics and, in expectation, promoting comparable distributions of measured and unmeasured confounding variables across experimental conditions ([Bhattacharyya et al., 2013](#); [Kunz et al., 2007](#); [Marcus, 2022](#); [Odgaard-Jensen et al., 2011](#)). This process is especially critical in sports science, where diverse factors such as training load, nutrition, genetics, and psychological variables can influence outcomes in unpredictable ways ([Halperin et al., 2015](#)). Although randomization minimizes selection bias and reduces accidental imbalances, it is a necessary but not sufficient safeguard against bias. Even when randomization is properly implemented, other sources of bias may still arise, so its contribution to validity and reproducibility depends on being combined with rigorous study design, allocation concealment, blinding where appropriate, and transparent reporting ([Miola et al., 2025](#); [Smalheiser, 2017](#)). Meta-epidemiological evidence from clinical trials indicates that inadequate randomization and lack of blinding may exaggerate treatment effects, with larger bias observed for subjectively assessed outcomes ([Wang et al., 2024](#); [Wood et al., 2008](#)). This issue is relevant to sport and exercise science because self-reported and perceptual outcomes, including athlete well-being, perceived exertion, muscle soreness, fatigue, pain, recovery status, motivation, and perceived readiness, are frequently used in applied research and athlete monitoring ([Duignan et al., 2020](#)).

However, despite its value, the implementation of randomization in sports science is far from straightforward. Misconceptions persist, such as the belief that randomization “fails” when groups are not perfectly balanced, whereas in reality, such imbalances reflect inherent variability rather than methodological error ([Owora et al., 2022](#)). Furthermore, the frequent reliance on small samples in elite athlete research can exacerbate imbalance and reduce statistical power, complicating the interpretation of results ([Bullock et al., 2023](#); [Landy, 2023](#)). Practical and ethical constraints also limit the feasibility of randomized controlled trials (RCTs) in competitive sport settings, where interventions may affect team dynamics or raise concerns about withholding effective treatments ([Bullock et al., 2023](#); [Louro et al., 2023](#)).

Although extensive methodological literature has addressed randomization in clinical trials and experimental research, there remains a need for an integrated synthesis focused specifically on its application within sport and exercise science ([Bullock et al., 2023](#); [Miola et al., 2025](#)). Applied sport research may involve methodological constraints that differ in degree from those encountered in conventional clinical trials, including restricted access to specialized athlete populations, relatively small eligible samples, team-based intervention delivery, competition and training schedules, and limited researcher control over concurrent training and recovery practices ([Bullock et al., 2023](#)). These characteristics do not alter the fundamental principles of randomization, but they may substantially influence the feasibility of allocation procedures, the appropriate unit of randomization, the risk of contamination, intervention adherence, analytical requirements, and the interpretation and generalizability of findings. Accordingly, this narrative review critically examines current issues surrounding randomization in sports science, clarifies common misconceptions, distinguishes allocation procedures from randomized trial designs and complementary causal-inference approaches, and considers context-appropriate methodological alternatives. By integrating general methodological principles with the specific practical constraints of sport and exercise research, this review aims to provide researchers with a clearer framework for designing, implementing, and interpreting rigorous studies in applied sport settings.

Methods of the Narrative Review

This article was conducted as a narrative review aimed at critically examining methodological issues related to randomization in sport and exercise science rather than as a systematic review. Relevant literature was identified through searches of PubMed, Scopus, Web of Science Core Collection, and SPORTDiscus, with the search

conducted up to 15 March 2026. The principal search concepts included combinations of terms related to randomization, random allocation, allocation concealment, randomized controlled trials, block randomization, stratified randomization, cluster randomization, crossover designs, adaptive randomization, Bayesian methods, stepped-wedge designs, quasi-experimental designs, Mendelian randomization, sports science, exercise science, and elite athletes. Relevant publications were selected on the basis of their methodological relevance to the conceptual, practical, ethical, or statistical issues addressed in this review, with particular attention to studies and methodological papers applicable to sport and exercise settings. Complete database-specific search strings and the total number of records identified at each stage were not prospectively recorded because the review was conducted using a narrative, purposive approach rather than a systematic-review protocol. No formal systematic-review protocol, exhaustive search strategy, duplicate screening procedure, or risk-of-bias assessment was undertaken; therefore, the literature included should be interpreted as a purposively selected methodological evidence base rather than a comprehensive systematic synthesis.

Understanding randomization in sports science

Randomization is a fundamental methodological tool in sports science that can strengthen, rather than ensure, the validity and reliability of experimental outcomes. Its contribution depends on being integrated with other rigorous design features, including appropriate blinding, allocation concealment, and adequate monitoring or control of relevant covariates such as nutrition, habitual physical activity, recovery status, and training load ([Preobrazenski et al., 2024](#)).

In experimental research, randomization refers to the assignment of participants or experimental units to study conditions according to a prespecified allocation procedure with known probabilities. Equal allocation, such as 1:1 assignment, is one common form, but it is not the defining requirement of randomization. Valid randomized designs may also use unequal allocation ratios, stratified or blocked allocation, minimization, or response-adaptive procedures, provided that the allocation mechanism is prespecified, implemented without investigator manipulation, and appropriately accounted for in the statistical analysis.

The inferential value of randomization lies not in guaranteeing identical groups at baseline, but in making treatment assignment independent of participant characteristics under the specified design. When properly implemented, randomization reduces systematic allocation bias and, in expectation, promotes comparable distributions of measured and unmeasured prognostic factors across experimental conditions. This supports exchangeability between groups and strengthens the internal validity of causal comparisons (["Randomization," 2023](#); [Shah & Vingan, 2023](#)).

In sports science, where small sample sizes, heterogeneous training backgrounds, and highly variable performance outcomes often complicate research, randomization is particularly important for reducing systematic allocation bias and improving the credibility of intervention effects. However, because chance imbalances may still occur, especially in small samples, randomization should be complemented by transparent reporting of baseline characteristics, appropriate adjustment for key prognostic variables when justified, and sensitivity analyses where necessary. The following sections distinguish random allocation procedures from randomized trial designs and complementary causal-inference approaches relevant to sport research settings.

Simple Randomization

Simple randomization involves assigning subjects to groups purely by chance, such as through a coin toss or a computer-generated sequence ([D. G. Altman & J. M. Bland, 1999](#); [Kang et al., 2008](#); [Rosenberger & Lachin, 2015](#)). Although this method is straightforward and minimizes researcher influence, it may result in unequal group sizes, particularly in small samples that are common in elite sports research, which in turn can compromise statistical power ([Bhattacharyya et al., 2013](#); [Shah & Vingan, 2023](#)).

Block Randomization

Block randomization addresses the limitations of simple randomization by dividing participants into blocks of predetermined size, within which subjects are randomly assigned ([Kang et al., 2008](#); [Rosenberger & Lachin, 2015](#)). This ensures a more even distribution of participants across groups at each stage of recruitment. It is especially useful in sports studies where trials are constrained by limited participant availability ([Azher et al., 2024](#); [Mahajan et al., 2023](#)).

Stratified Randomization

Stratified randomization enhances comparability by categorizing participants into strata based on key variables, such as age, sex, competitive level, playing position, or playing status before random assignment within each stratum ([Kang et al., 2008](#); [Rosenberger & Lachin, 2015](#)). This ensures balance across important covariates that might otherwise confound results, which is critical in sports research where performance outcomes are strongly influenced by demographic and physiological differences ([Mahajan et al., 2023](#); [Shi & Li, 2024](#)).

Cluster-Randomized Trial Design

Cluster randomization allocates groups, rather than individuals, to different study arms. In sports science, this may involve randomizing entire teams, schools, training squads, or clubs to different interventions. This approach is useful when interventions are delivered collectively, when contamination between participants is likely, or when individual-level randomization is impractical.

However, cluster-randomized designs require specific design and analytical considerations because observations within the same cluster are typically correlated ([Brown et al., 2015](#)). Analyses should account for the intracluster correlation structure, for example through mixed-effects models, generalized estimating equations, or appropriately specified cluster-level analyses. In addition, sample-size calculations and statistical inference should reflect the number of clusters, cluster size, intracluster correlation, and the resulting degrees of freedom, because treating clustered observations as independent can underestimate standard errors and inflate type I error ([Dwivedi, 2025](#)).

Crossover Randomized Trial Design

Crossover designs allow each participant to receive two or more interventions across successive study periods, with the order of interventions assigned according to a randomized sequence. Because each participant contributes data under multiple conditions, this design can reduce between-participant variability and improve statistical efficiency, provided that the intervention effects are transient and that the outcome can return to baseline between periods.

Crossover trials require explicit consideration of period effects and within-subject correlation in the design and analysis, commonly through models that include treatment, period, and participant-level effects. Adequate washout periods should be planned when residual effects are biologically plausible. If meaningful carryover effects cannot be ruled out or adequately prevented by design, a crossover design may be inappropriate, and a parallel-arm design or a different research question should be considered instead ([Dwivedi, 2025](#)).

Mendelian Randomization as a Complementary Observational Causal-Inference Method

Mendelian randomization should be distinguished from trial-design randomization procedures such as simple, block, stratified, or cluster randomization. Unlike these procedures, Mendelian randomization is not implemented by investigators to allocate participants to experimental conditions. Rather, it is an observational instrumental-variable approach that uses genetic variants as instruments to estimate the potential causal effect of an exposure on an outcome ([Birney, 2022](#); [Emdin et al., 2017](#); [Sanderson et al., 2022](#); [Smith & Ebrahim, 2004](#); [Tudball et al., 2022](#); [VanderWeele et al., 2014](#); [Zheng et al., 2017](#)).

Its validity depends on the core instrumental-variable assumptions. First, the genetic instrument must be associated with the exposure of interest, known as the relevance assumption. Second, the instrument should be independent of unmeasured confounders of the exposure–outcome relationship, known as the independence assumption. Third, the instrument should influence the outcome only through the exposure and not through alternative biological pathways, known as the exclusion-restriction assumption. These assumptions are not guaranteed by the random assortment of alleles at conception and require explicit empirical and biological justification in each application. In sports science, Mendelian randomization may be useful for exploring causal hypotheses related to nutrition, body composition, performance traits, recovery, and injury susceptibility, particularly when randomized trials are infeasible or unethical. However, it should not be presented as a substitute for experimental randomization. Its credibility depends on careful instrument selection, assessment of pleiotropy, sensitivity analyses, and transparent discussion of potential violations of instrumental-variable assumptions. Accordingly, Mendelian randomization is best framed as a complementary observational causal-inference method rather than as a randomization procedure within experimental design.

Practical Implementation: Software Tools for Randomization

In recent years, various software tools have been developed to facilitate this process, each offering distinct features that enhance methodological rigor and reproducibility. These tools range from specialized R and Julia packages for advanced users to intuitive web-based applications that support researchers with limited statistical expertise. For instance, randomizeR (R package) provides a comprehensive suite for generating randomization sequences and assessing procedures under different constraints, making it particularly valuable for trials that demand flexibility across multiple designs ([Uschner et al., 2018](#)).

Several dedicated software packages and web-based platforms are available to support sequence generation, minimization, covariate-adaptive allocation, and response-adaptive randomization, including randomizeR, RRApp, OxMaR, carat, RARtool, and Incertus.jl ([Ma et al., 2023](#); [O'Callaghan, 2014](#); [Ryznik & Sverdlov, 2024](#); [Ryznik et al., 2015](#); [Tu & Benn, 2018](#)). Selection of a tool should be guided by the allocation method, study design, reproducibility requirements, available infrastructure, and statistical expertise of the research team.

Widely used in applied research, GraphPad QuickCalcs provides a simple web-based tool for random assignment of subjects into groups, making it particularly useful in smaller sports science studies where rapid and transparent randomization is needed without complex statistical coding ([Saghaei, 2011](#)). In addition, services such as the Web Service for Randomization ([Bonotis et al., 2021](#)) provide REST-based integration with broader IT systems, making them suitable for large-scale or multi-site trials. Importantly, the integration of artificial intelligence and machine learning in randomization is an emerging trend, with potential to enhance efficiency and statistical power ([Sharma & Singh, 2023](#)).

However, such innovations must be adopted cautiously, with attention to their implications for trial design and interpretation. Ultimately, the thoughtful use of dedicated randomization software enhances transparency, minimizes bias, and aligns with best practices for reproducibility in both clinical and sports science research ([Arslan et al., 2019](#)).

The methodological approaches discussed in this review should be distinguished according to their role within the research process. Random allocation procedures, such as simple, block, stratified, and response-adaptive randomization, determine how experimental units are assigned to study conditions. Randomized trial designs, including parallel-group, cluster-randomized, crossover, and stepped-wedge cluster-randomized trials, define the broader structure through which randomized comparisons are implemented. By contrast, quasi-experimental designs do not rely on investigator-controlled random allocation and instead support causal interpretation through specific design features and identifying assumptions. Bayesian methods represent a statistical inferential framework that may be incorporated within randomized or non-randomized studies, whereas Mendelian randomization is an observational instrumental-variable approach to causal inference and is conceptually distinct from experimental randomization. Pragmatic trials are best considered a design orientation emphasizing evaluation under real-world conditions and may themselves be randomized or non-randomized. These distinctions are important because each methodological category addresses a different aspect of study design, allocation, analysis, or causal inference. Their principal characteristics, advantages, limitations, and applications in sport and exercise science are summarized in Table 1.

Table 1 - Overview of methodological approaches relevant to randomization and causal inference in sports science research

Methodological category	Method / design	Core principle	Advantages	Limitations / challenges	Typical application in sports science
Random allocation procedure	Simple randomization	Participants are assigned to study groups according to a chance-based allocation sequence, typically with	Easy to implement; limits researcher influence over allocation.	May produce unequal group sizes or chance baseline imbalances, particularly in small samples.	General training or intervention studies with adequate recruitment.

		equal or prespecified probabilities.			
Random allocation procedure	Block randomization	Participants are randomized within prespecified blocks to maintain approximate balance in group sizes during recruitment.	Helps maintain similar group sizes throughout enrollment; useful in small or staggered samples.	Fixed or small block sizes may make allocation predictable if concealment is inadequate.	Small-sample athlete trials or studies with staggered recruitment.
Random allocation procedure	Stratified randomization	Participants are classified according to selected prognostic variables and then randomized within each stratum.	Reduces the probability of large imbalances in important measured prognostic variables.	Requires prespecification of relevant strata; excessive stratification may be impractical in small samples.	Studies in which sex, baseline performance, competitive level, or another prognostic variable is expected to influence outcomes.
Random allocation procedure	Response-adaptive randomization	Allocation probabilities for future participants are modified according to prespecified rules based on accumulating trial data.	May increase allocation to interventions showing more favorable interim responses; potentially useful in hard-to-recruit populations.	Statistically and operationally complex; vulnerable to early random variation; requires prespecified rules and appropriate analysis.	Selected pilot or experimental studies in specialized athlete populations when sequential recruitment is possible.
Randomized trial design	Parallel-group randomized trial	Participants are randomly allocated to one study arm and remain in that arm for the intervention period.	Clear between-group comparison; straightforward interpretation when implemented appropriately.	May require larger samples than within-subject designs; chance imbalance may remain in small samples.	Training, nutrition, recovery, rehabilitation, or performance interventions.
Randomized trial design	Cluster-randomized trial	Intact groups, such as teams, squads, schools, or clubs, are randomized rather than	Reduces contamination between participants; compatible with team-level interventions.	Requires accounting for intracluster correlation and a sufficient number of clusters;	Team-based training, injury-prevention, educational, or organizational interventions.

		individual participants.		reduced statistical efficiency may occur.	
Randomized trial design	Crossover randomized trial	Participants receive two or more interventions across successive periods, with the order of interventions randomized.	Reduces between-participant variability; can improve efficiency in small samples.	Requires consideration of carryover, period effects, washout, reversibility, and within-subject correlation.	Acute recovery, supplementation, equipment, physiological, or short-term performance interventions.
Randomized trial design	Stepped-wedge cluster-randomized trial	Clusters cross from control to intervention at different time points, with the order or timing of rollout randomized.	Allows all clusters eventually to receive the intervention; useful for staged implementation.	Requires modeling of calendar time, within-cluster correlation, secular trends, contamination, and possible treatment-by-time effects.	Team- or organization-level interventions introduced progressively across squads or clubs.
Non-randomized / quasi-experimental design	Quasi-experimental designs	Intervention assignment is not determined by investigator-controlled randomization; causal interpretation relies on design structure and explicit identifying assumptions.	Feasible when randomization is impractical, unethical, or incompatible with operational constraints.	More vulnerable to confounding and selection bias; causal interpretation depends on assumptions that may not be fully testable.	Applied team-sport interventions in which coaching or organizational decisions determine exposure.
Non-randomized / quasi-experimental design	Propensity-score approaches	Participants are matched, weighted, or adjusted according to the estimated probability of receiving an intervention based on measured covariates.	Can improve comparability of intervention groups on observed characteristics.	Does not control unmeasured confounding; depends on adequate measurement and model specification.	Observational comparisons of training, rehabilitation, or injury-prevention interventions.
Non-randomized /	Regression discontinuity	Treatment assignment is	Can support strong causal	Requires sufficient	Selection, eligibility, or

quasi-experimental design		determined by whether a continuous eligibility variable falls above or below a prespecified threshold.	inference near the assignment threshold when assumptions are met.	observations around the cutoff and no manipulation of the assignment variable.	intervention decisions determined by performance or clinical thresholds.
Non-randomized / quasi-experimental design	Difference-in-differences	Changes in outcomes over time are compared between exposed and comparison groups.	Useful when interventions are implemented naturally in one group but not another.	Relies strongly on the parallel-trends assumption and may be affected by time-varying confounding.	Evaluation of policy, training, medical, or organizational changes across teams or seasons.
Statistical / inferential framework	Bayesian inference	Prior information is combined with observed data to generate posterior distributions for parameters or treatment effects.	Provides direct probability statements about effects and supports prespecified adaptive decision rules.	Results may be sensitive to prior specification and model assumptions, particularly in small samples.	Trials in which uncertainty, prior knowledge, or adaptive stopping decisions are important.
Observational causal-inference method	Mendelian randomization	Genetic variants are used as instrumental variables to estimate the potential causal effect of an exposure on an outcome.	Can provide complementary evidence on causal hypotheses when experimental manipulation is infeasible.	Depends on instrument relevance, independence, exclusion-restriction assumptions, pleiotropy, ancestry, and adequate statistical power.	Exploration of causal relationships involving genetic predisposition, body composition, metabolic traits, injury susceptibility, or performance-related exposures.
Broader design orientation	Pragmatic trial orientation	Evaluates an intervention under conditions intended to reflect routine practice; the study may be randomized or non-randomized	High practical relevance and ecological applicability; accommodates real-world implementation constraints.	Greater contextual heterogeneity and variation in adherence or implementation may complicate interpretation.	Applied interventions conducted within normal training, competition, rehabilitation, or organizational environments.

Practical limitations in sports science contexts

Challenges of Small Sample Sizes in Elite Athlete Research

A persistent limitation in sports science is the difficulty of recruiting large samples, particularly when the target population is elite athletes. Elite athletes are relatively scarce, tightly scheduled, and often inaccessible for lengthy interventions. However, the implications of small sample size should be distinguished carefully from the function of randomization itself. Randomization remains a valid allocation procedure regardless of sample size when it is properly implemented; what small samples primarily affect are the precision of effect estimates, statistical power, and the probability of chance baseline imbalances.

In small trials, estimated intervention effects are typically less precise, confidence intervals are wider, and the probability of failing to detect a true effect is increased. Small samples may also produce chance imbalances in important prognostic variables across study arms, even when allocation is randomized. These imbalances do not indicate that randomization has failed, but they can complicate interpretation and may justify prespecified covariate adjustment, stratified or blocked randomization, transparent baseline reporting, and sensitivity analyses when appropriate ([Baker et al., 2022](#); [Hecksteden et al., 2022](#)).

External validity should also be treated as a separate issue from randomization. The generalizability of findings from non-elite, recreational, or mixed athletic populations to elite athletes does not depend solely on whether elite athletes were included in the sample. Rather, it depends on whether the causal mechanisms underlying the intervention effect are expected to operate similarly in the target population. Therefore, claims that findings cannot transfer to elite athletes should be supported by substantive physiological, biomechanical, behavioral, or contextual arguments, rather than by representativeness alone.

To address the practical constraints of elite-sport research, alternative methodological approaches such as single-subject experimental designs, repeated-measures designs, n-of-1 studies, and statistical process control techniques may be useful when the research question concerns within-athlete change over time ([Kinugasa, 2013](#); [Sands et al., 2019](#)).

These approaches can improve individual-level interpretability and ecological relevance, but they do not automatically solve problems of external validity or causal inference. When research questions require estimation of between-group effects, multiple interacting variables, or heterogeneous treatment responses, larger samples, longer follow-up, multi-site collaboration, or carefully justified analytical strategies may still be necessary to generate robust and interpretable findings ([Kinugasa, 2013](#); [Kinugasa et al., 2004](#); [Robinson et al., 2024](#); [Tweedy et al., 2024](#)).

Issues with Protocol Adherence and Participant Dropout

Even when elite athletes can be recruited into studies, maintaining adherence to experimental protocols presents another major limitation. Athletes operate within demanding schedules that include training camps, competitions, travel, and recovery, all of which can disrupt research procedures ([Burgess, 2017](#)). Strict intervention timelines may clash with coaching priorities, athletes' schedules, or medical requirements, leading to partial compliance. This non-adherence can dilute the true effect of an intervention, reduce statistical power, and compromise the interpretability of results. In randomized studies, deviations from assigned interventions may also undermine the benefits of randomization, particularly when non-compliance differs systematically between groups. Moreover, dropout is a recurring challenge. Injuries, performance pressures, transfers, or changes in team selection often result in athletes withdrawing from studies before completion. Attrition not only reduces sample size but can introduce systematic bias if dropouts differ in important ways from those who remain. These challenges underscore the need for flexible study designs that can accommodate real-world disruptions while still collecting reliable data ([Bullock et al., 2023](#)).

Constraints in Real-World Team and Competition Environments

Conducting research in team or competition settings adds further complexity. Unlike laboratory conditions, real-world sporting environments are inherently dynamic and unpredictable, and researchers have limited control over numerous contextual variables. Team schedules change at short notice, travel demands alter recovery opportunities, and coaches may adjust training schedules based on tactical priorities, team needs, or other factors, rather than research protocols ([Burgess, 2017](#)). Such variability introduces uncontrolled confounding variables, making it difficult to isolate the true effect of an intervention. Furthermore, interventions tested in team sports often interact with collective strategies, player rotations, individual training needs, or match intensity, which reduces the ability to attribute outcomes to the intervention itself. While these constraints enhance ecological validity by reflecting the actual conditions in which athletes perform, they simultaneously complicate the translation of findings into universally applicable recommendations. Finally, high-performance sport environments may face competing demands for limited time, personnel, and resources, with immediate performance, health, and operational priorities potentially constraining participation in research activities. This should be understood as a possible implementation barrier rather than as a general lack of interest in research among sport organizations. Researchers therefore face the delicate task of designing interventions that are methodologically rigorous yet adaptable enough to survive the complexities of professional sporting contexts ([Coutts, 2020](#)).

Allocation Concealment Difficulties

Another limitation arises from the challenge of maintaining allocation concealment in sports science research. Allocation concealment refers to preventing investigators, coaches, recruiters, or other personnel involved in enrollment from knowing or predicting the upcoming group assignment before a participant is entered into the study. Its purpose is to reduce allocation-related selection bias by preventing conscious or unconscious manipulation of enrollment based on the anticipated assignment ([Kim & Shin, 2014](#)).

Maintaining allocation concealment may be particularly challenging in elite sport contexts. Evidence from healthcare trials indicates that inadequate allocation concealment can introduce systematic bias, and similar risks may arise in sports science when coaches, practitioners, or researchers have strong preferences regarding which athletes receive a given intervention ([Odgaard-Jensen et al., 2011](#)). For example, small team sizes, close working relationships, and competitive priorities may make it difficult to separate enrollment decisions from knowledge or expectations about the allocation sequence. When interventions could affect training adaptation, recovery, or team performance, coaches may also resist random assignment or seek to assign athletes according to tactical or practical needs.

Allocation concealment should be distinguished from blinding. Concealment protects the allocation process before and during enrollment, whereas blinding protects the conduct and assessment of the trial after allocation has occurred. In many sports science interventions, blinding athletes and coaches may be difficult or impossible because the intervention, such as a training program, recovery method, or nutritional protocol, is visible to participants. This lack of blinding may generate expectancy effects, behavioral changes, or performance bias, but these are post-allocation threats and should not be conflated with allocation-related selection bias ([Bullock et al., 2023](#)).

Although methods such as centralized randomization, independent allocation by a third party, or sequentially numbered, opaque, sealed envelopes can support allocation concealment, their feasibility may be constrained in high-performance environments where competitive outcomes take priority. To address these constraints, a pragmatic trial orientation may be useful within appropriately designed randomized or non-randomized studies, provided that the allocation procedure, concealment mechanism, baseline characteristics, and any deviations from the planned assignment process are transparently reported ([Bullock et al., 2023](#)).

Common misconceptions and methodological pitfalls

Despite being a cornerstone of rigorous research methodology, randomization is often subject to misconceptions and errors in implementation that can undermine its purpose. Methodological evidence indicates that inadequate randomization or poor allocation concealment can distort estimated intervention effects, leading to either overestimation or underestimation rather than necessarily inflated effects. In sports science, such bias may also attenuate the apparent efficacy of an intervention, increase uncertainty around individual treatment responses, or

reduce confidence in the interpretation of modest-to-moderate effects commonly reported in the field ([Preobrazenski et al., 2024](#)). Therefore, rigorous implementation and transparent reporting of randomization procedures remain essential ([Douglas G Altman & J Martin Bland, 1999](#); [Kunz et al., 2007](#); [Odgaard-Jensen et al., 2011](#)).

Quasi-random or systematic allocation mistaken for randomization

One of the most common problems in experimental design is the use of quasi-random or systematic allocation procedures that may appear similar to randomization but are actually determined by predictable rules. Examples include alternation, allocation by admission order, assignment according to date of birth, or date-based allocation. Although these approaches may be used in sports science because of limited infrastructure, restricted access to elite athletes, or small eligible populations, they should not be presented as equivalent to random allocation.

Quasi-random and systematic allocation procedures are vulnerable because the next assignment may be predictable before enrollment. This predictability can compromise allocation concealment and increase the risk of allocation-related selection bias if investigators, coaches, or practitioners can consciously or unconsciously influence which participants enter each group. When such procedures are unavoidable, researchers should clearly report the recruitment and allocation mechanisms, avoid describing the study as randomized, acknowledge the associated risk of selection bias, and interpret causal comparisons cautiously ([Douglas G Altman & J Martin Bland, 1999](#); [Kunz et al., 2007](#); [Rosenberger & Lachin, 2015](#); [Vorland et al., 2021](#)).

Randomization, by contrast, requires a prespecified allocation mechanism based on chance, with known allocation probabilities and an assignment sequence that cannot be predicted or manipulated before enrollment. Equal allocation, such as 1:1 assignment, is only one possible form of randomization; unequal allocation ratios and adaptive randomization may also be valid when prespecified and properly analyzed. Misclassifying quasi-random or nonrandom allocation as randomization has been documented in areas such as nutrition and obesity research and can undermine the credibility, reproducibility, and internal validity of intervention studies ([Senn, 2013](#); [Shaw et al., 2012](#); [Vorland et al., 2021](#)).

Post hoc group adjustments and manipulation of allocation

A further methodological weakness occurs when researchers alter the prespecified allocation after randomization. A further methodological weakness occurs when researchers make post hoc changes to the prespecified allocation, such as reassigning participants to achieve greater group balance or modifying allocation ratios during the trial, because these investigator-driven changes compromise the integrity of the original randomization process and may introduce systematic bias ([Rosenberger & Lachin, 2015](#)). Post hoc adjustments, such as reassigning participants to achieve more balanced groups or modifying allocation ratios during the trial, introduce systematic bias by compromising the integrity of the original randomization process. These practices distort baseline equivalence and contradict the intent-to-treat principle, which requires that all participants remain in their originally assigned groups ([Shaw et al., 2012](#)). Beyond undermining internal validity and reproducibility, post-hoc reassignment or manipulation of group allocation breaks the link between the study design and the statistical analysis. In a randomized trial, significance tests and p-values are calibrated to the reference distribution implied by the prespecified allocation procedure and analysis plan. If participants are reassigned after allocation, or if allocation rules are changed without being incorporated into the analysis, the resulting test statistics may no longer be evaluated against the correct reference distribution. This can produce misleading standard errors, confidence intervals, and p-values, and may exaggerate apparent treatment effects, particularly in small-sample studies where chance imbalances are more influential ([Owora et al., 2022](#)).

Under-reporting or misreporting randomization procedures

A frequent issue in published research is insufficient detail on how randomization was conducted. While randomization itself cannot “fail,” improper implementation or incomplete reporting can obscure methodological weaknesses ([Owora et al., 2022](#)). Lack of transparency not only hinders replication but also precludes accurate external validation and the inclusion of the study in high-quality systematic reviews or meta-analyses. In many instances, trials labeled as 'randomized' have been found to employ quasi-random (e.g., alternation, date of birth) or convenience allocation methods, which are inherently prone to predictability and bias ([Vorland et al., 2021](#)). Adhering to reporting standards such as CONSORT is therefore vital to maintain accountability and prevent misrepresentation ([Hopewell et al., 2025](#)).

Misinterpretation of statistical outputs due to design flaws

Finally, flawed randomization introduces downstream problems in data analysis and interpretation. For example, failing to account for clustering in cluster-randomized trials renders standard inferential tests invalid, leading to inflated type I error rates ([Donner & Klar, 2004](#)). A related misconception is that successful randomization should necessarily produce balanced baseline characteristics. Randomization does not guarantee balance in any single realized sample, particularly in small trials. Its inferential value instead derives from the prespecified chance-based allocation mechanism, which supports valid estimation and hypothesis testing under the design. Chance baseline differences should therefore be interpreted as possible features of randomized allocation rather than evidence that randomization has “failed” ([Senn, 2013](#)). Misunderstandings of these nuances can result in overconfidence in causal claims or erroneous generalizations.

Collectively, pseudo-random allocation, post-hoc manipulation of assignment, inadequate reporting, and design–analysis inconsistencies can compromise causal interpretation. Clear pre-specification, appropriate concealment, faithful implementation of the allocation mechanism, and transparent reporting are therefore essential for preserving the inferential advantages of randomized designs.

Ethical and logistical challenges

Randomized controlled trials (RCTs) in sports science research present substantial ethical and logistical challenges. One central dilemma arises when interventions are withheld from control groups. If an intervention is believed to be beneficial, assigning some participants to receive no treatment, or a placebo, may be perceived as violating the principle of non-maleficence. This concern is heightened when effective training methods or rehabilitation strategies are available, as withholding these could compromise athlete well-being or performance ([Louro et al., 2023](#); [Ménard, 2025](#)). Such dilemmas create tension between the scientific need for robust controls and the ethical duty to protect participants.

Resistance from coaches and teams to random allocation is another frequent challenge. In elite and professional settings, stakeholders may be unwilling to accept randomization that disrupts established training routines or potentially disadvantages their athletes. Coaches may view random allocation as interfering with performance goals, particularly in competitive contexts where even minor disruptions can affect outcomes ([Bullock et al., 2023](#)). This resistance complicates trial implementation and can lead to poor adherence or participant dropout.

Relatedly, there is often pressure to deliver beneficial interventions to all participants rather than restricting them to an intervention arm. This pressure is both ethical and pragmatic: teams and athletes want equal access to innovations that could enhance performance or reduce injury risk. The issue of post-trial access further compounds this, as participants in the control group may feel disadvantaged if they never receive the intervention, raising concerns about fairness and justice ([Colli et al., 2014](#); [Prost et al., 2015](#)).

Particular ethical considerations arise when research involves youth, injured, or elite athletes. In youth sport research, investigators should ensure age-appropriate assent together with parent or legal-guardian consent where required, while clearly communicating the potential risks and benefits of participation ([Harriss et al., 2022](#)). For injured athletes, withholding a potentially effective rehabilitation protocol raises questions about harm and recovery. In elite populations, where careers and contracts may hinge on performance and health, the stakes of trial participation are exceptionally high, making randomization ethically fraught and logistically difficult ([Hecksteden et al., 2022](#); [Mtande et al., 2024](#)).

Overall, randomized controlled trials remain a central design for estimating causal effects of interventions when randomization is feasible and appropriately implemented, but their application in sports science must balance methodological rigor with ethical and practical considerations. Methodological approaches such as pragmatic trial frameworks and prespecified adaptive designs may help address these challenges while retaining appropriate experimental rigor and accommodating the practical demands of athletic contexts ([Bullock et al., 2023](#); [Flory & Karlawish, 2012](#)).

Alternative and complementary designs and methodological approaches

A range of complementary methodological approaches can be used to strengthen causal inference or address practical constraints in sport and exercise research, including non-randomized causal-inference methods, Bayesian frameworks, adaptive trial designs, and alternative randomized trial structures.

Mendelian Randomization for Exploring Causality

Mendelian randomization (MR) leverages genetic variants as instrumental variables to infer causality between exposures and outcomes, functioning as a “natural experiment” based on the random assortment of alleles at conception ([Burgess et al., 2019](#); [Davies et al., 2018](#)). When its instrumental-variable assumptions are adequately satisfied, Mendelian randomization can reduce susceptibility to confounding and reverse causation relative to conventional observational analyses, thereby providing complementary evidence for causal relationships in complex biological and behavioral domains ([Birney, 2022](#); [Emdin et al., 2017](#); [Sanderson et al., 2022](#); [Smith & Ebrahim, 2004](#); [Tudball et al., 2022](#); [VanderWeele et al., 2014](#); [Zheng et al., 2017](#)). However, recent commentary has warned of a growing credibility crisis in Mendelian randomization research, due to methodological misuse and lack of critical validation of causal claims ([Burgess et al., 2024](#); [Gill et al., 2024](#)). In sports science, MR may offer limited but potentially useful opportunities to explore causal pathways linking genetic predispositions with training outcomes or injury risk. However, given the methodological constraints discussed in this section, such applications should be interpreted cautiously and considered complementary to, rather than a replacement for, well-designed experimental and observational research.

Practical case: Stratification using multivariate phenotypic profiles: In small elite-athlete trials, stratified or covariate-adaptive randomization may incorporate prespecified multivariate phenotypic profiles when these are biologically meaningful and prognostically relevant. For example, athletes could be classified according to a limited number of baseline physiological characteristics and subsequently randomized within phenotype strata. This approach may reduce the probability of severe imbalance in measured prognostic factors but should not be considered a new form of randomization. Its validity depends on pre-specification, reproducibility of the phenotype classification, adequate numbers within strata, and appropriate analysis. Overstratification should be avoided, particularly in small samples.

Quasi-Experimental Designs

When randomized controlled trials are not feasible because of ethical, logistical, or operational constraints, quasi-experimental designs may provide useful alternatives for causal inference in applied sports science ([Bärnighausen, Röttingen, et al., 2017](#); [Geldsetzer & Fawzi, 2017](#)). However, these approaches should not be described as approximating random allocation. Unlike randomized trials, quasi-experimental designs do not generate treatment assignment through a known chance mechanism. Instead, they attempt to reduce bias by using observed data structures, comparison groups, timing of exposure, or eligibility rules to support causal interpretation under explicit identification assumptions ([Bärnighausen, Oldenburg, et al., 2017](#); [Bärnighausen, Tugwell, et al., 2017](#)).

Methods such as propensity score matching, regression discontinuity, and difference-in-differences rely on different assumptions and should not be treated as interchangeable substitutes for randomization. Propensity score methods condition on measured covariates and therefore require the assumption that there is no unmeasured confounding after adjustment. Regression discontinuity designs require the assumption that units close to the assignment threshold are comparable and that potential outcomes vary continuously around the cutoff. Difference-in-differences designs require the assumption that, in the absence of the intervention, treated and comparison groups would have followed parallel outcome trends.

These approaches may be valuable in field-based sports research where randomization could disrupt team dynamics, competitive fairness, or normal training operations ([Fröhlich et al., 2009](#)). For example, propensity score methods can adjust for measured baseline differences in athlete performance, training history, or training load, thereby improving comparability on observed characteristics ([Scheier, 2010](#)). However, they do not eliminate bias from unmeasured or poorly measured confounders and should not be presented as full or unbiased replacements for randomized designs. Their credibility depends on transparent reporting of the assignment mechanism, careful justification of the identification assumptions, covariate balance diagnostics where applicable, and sensitivity analyses assessing the robustness of conclusions to plausible assumption violations.

Practical case: A professional football club may introduce an individualized hamstring injury-prevention program preferentially to players considered at higher risk, making individual randomization impractical. In this setting, a quasi-experimental design could compare exposed and non-exposed players while adjusting for measured baseline differences such as previous injury, playing position, eccentric strength, sprint exposure, match minutes, and training load. Propensity-score methods or, when suitable longitudinal data are available, a difference-in-differences approach may help reduce bias. However, residual confounding remains possible, and

causal interpretation should therefore remain cautious and explicitly linked to the assumptions of the chosen design.

Bayesian Inference and Adaptive Trial Designs

Bayesian inference and adaptive trial designs are related but conceptually distinct methodological approaches. Bayesian inference is a statistical framework in which prior information is combined with observed data to generate posterior distributions for parameters or treatment effects. It can be applied within conventional randomized trials, adaptive trials, and non-randomized studies and does not, by itself, determine how participants are allocated to study conditions ([Bautista et al., 2018](#); [Bittl & He, 2017](#); [Wijeysundera et al., 2009](#); [Yarnell et al., 2021](#)). Adaptive trial designs, by contrast, permit prespecified modifications to aspects of an ongoing trial on the basis of accumulating information. Depending on the design, these modifications may involve sample size, treatment arms, stopping rules, or allocation probabilities ([Bhatt & Mehta, 2016](#); [Chow & Chang, 2008](#); [Edson, 2017](#)). Response-adaptive randomization is one specific adaptive allocation strategy in which the probabilities of assigning future participants to different intervention groups change according to prespecified rules based on accumulating trial data ([Proper et al., 2021](#); [Rosenberger & Lachin, 2015](#)).

Bayesian methods may be used to support adaptive decision rules, but Bayesian inference and adaptive randomization should not be treated as synonymous. For example, a trial may use Bayesian interim monitoring without changing allocation probabilities, whereas a response-adaptive trial may modify allocation probabilities according to accumulating outcomes. In either case, adaptations should be prespecified, supported by appropriate statistical modeling and simulation of operating characteristics, and transparently reported. Neither Bayesian inference nor adaptive allocation eliminates the limitations associated with sparse data; in small athlete samples, uncertainty may remain substantial and conclusions may be sensitive to prior specification, model assumptions, and early random variation.

Practical case-Bayesian adaptive stopping for harm in altitude training: In an altitude-training trial involving elite athletes, investigators could prespecify Bayesian interim monitoring rules for evidence of harm or maladaptation. If the posterior probability of clinically meaningful harm in a high-dose hypoxia arm exceeds a predefined threshold, that arm could be suspended or discontinued according to a prespecified protocol. This illustrates adaptive stopping for safety rather than response-adaptive randomization, in which allocation probabilities for future participants would change according to accumulating outcome data. In both cases, the decision rules, interim analyses, thresholds, and statistical models should be specified in advance and transparently reported.

Stepped-Wedge Cluster-Randomized Designs in Team Sports

A stepped-wedge cluster-randomized trial is a randomized trial design in which intact clusters, such as teams, clubs, schools, or training groups, transition from a control or usual-practice condition to an intervention at different prespecified time points, with the order or timing of rollout randomized ([Hargreaves et al., 2015](#); [Hemming et al., 2015](#); [Thompson et al., 2017](#)). Accordingly, stepped-wedge designs should not be considered merely as alternatives when randomization is infeasible; rather, they represent a form of cluster randomization that may be particularly useful when staged implementation is operationally necessary or when all participating clusters are intended eventually to receive the intervention. The design may be especially relevant in applied sports settings where interventions must be distributed across teams, squads, or training environments in a planned and equitable manner ([Patterson et al., 2022](#); [Salway et al., 2025](#)). However, stepped-wedge designs introduce important analytical and inferential complexities. Outcomes in sport often change over time because of secular trends such as seasonal progression, training periodization, fixture congestion, injury burden, coaching changes, or environmental conditions. These time effects must be modeled explicitly because they can be confounded with the intervention rollout.

A further methodological concern is identifiability when secular trends interact with treatment-effect heterogeneity over time. If the intervention effect differs according to season phase, accumulated fatigue, competitive schedule, or time since implementation, it may be difficult to distinguish the effect of the intervention from underlying temporal changes. Therefore, stepped-wedge studies should prespecify how time will be modeled, consider treatment-by-time or exposure-duration effects when biologically plausible, account for within-cluster correlation, and conduct sensitivity analyses assessing whether conclusions are robust to alternative assumptions about secular trends and time-varying treatment effects ([Copas et al., 2015](#); [Hussey & Hughes, 2007](#)).

Collectively, alternative and complementary designs expand the methodological toolkit available to sports and health researchers (Hemming et al., 2018; Li & Wang, 2022). However, they should not be viewed as automatically strengthening causal inference. Each design carries distinct assumptions, advantages, and vulnerabilities. The choice of design should therefore be guided by the research question, the assignment mechanism, the plausibility of the identifying assumptions, available resources, and the balance between methodological rigor and practical feasibility (Bullock et al., 2023; Hemming et al., 2015; Miola et al., 2025).

Practical case: A stepped-wedge cluster-randomized design could be used to evaluate a sleep and recovery program across multiple teams or squads when simultaneous implementation is not feasible. Teams would begin under usual practice and cross to the intervention at randomly assigned rollout times until all clusters receive the program. This design permits comparisons between exposed and not-yet-exposed clusters while accommodating staged implementation. However, analyses must account for calendar time, within-cluster correlation, secular trends, repeated measurements, and potential contamination between teams.

Recommendations for researchers

To advance rigor and applicability in sport and exercise science, researchers must adopt practices that enhance transparency, replicability, and ethical integrity. Several methodological recommendations are essential for strengthening the credibility and impact of future studies. Figure 1 provides a practical decision framework to guide researchers in determining whether randomization is feasible and appropriate and, accordingly, selecting a suitable randomized trial design, random allocation procedure, or complementary causal-inference approach according to the characteristics and constraints of the research context.

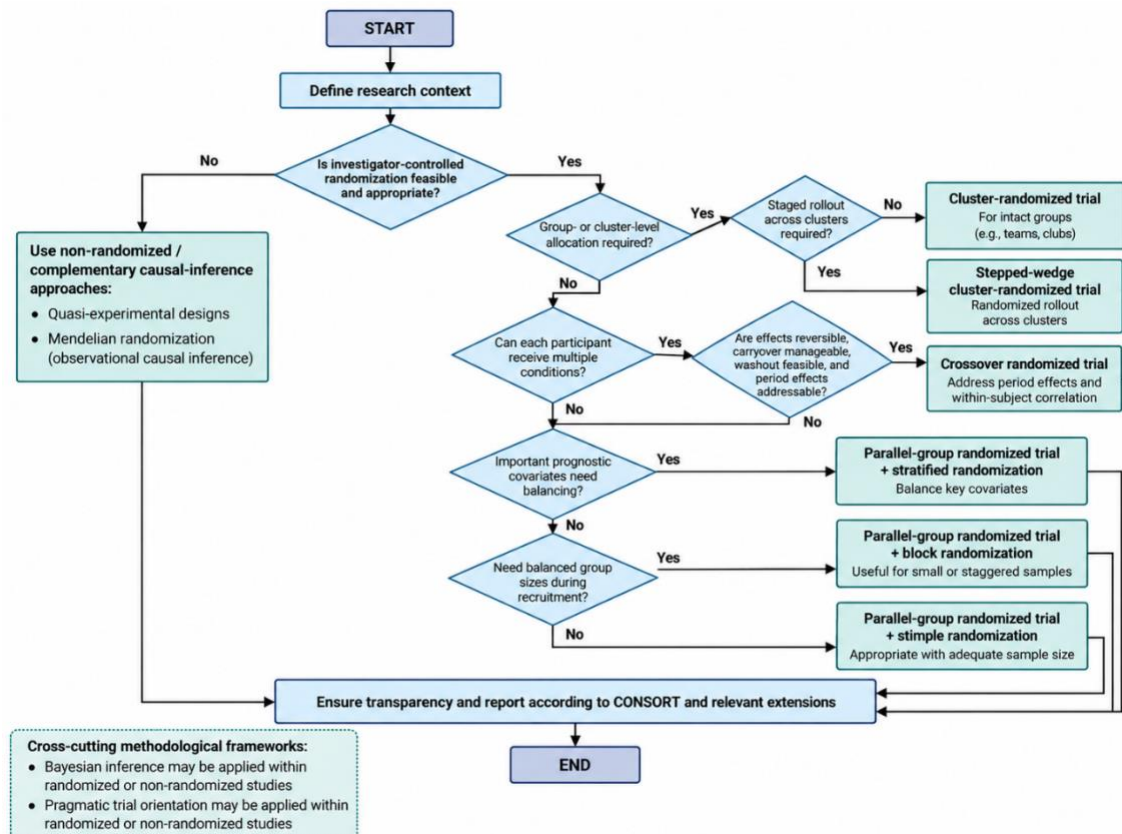


Figure 1. Decision framework for selecting randomized trial designs, allocation procedures, and complementary methodological approaches in sports science research. The framework distinguishes randomized trial designs from random allocation procedures and non-randomized causal-inference approaches. Crossover suitability additionally requires consideration of reversibility, carryover, washout feasibility, and period effects. Stepped-wedge designs are classified as cluster-randomized trials when rollout timing is randomized. Bayesian inference and pragmatic trial orientation are presented as cross-cutting methodological frameworks because they may be incorporated within

randomized or non-randomized studies, whereas Mendelian randomization is classified separately as an observational causal-inference method.

Transparent Reporting

Researchers should adhere to established reporting guidelines such as CONSORT ([Hopewell et al., 2025](#)) and SPIRIT, which promote transparency, completeness, and reproducibility in randomized trial reporting and protocol development.

Transparent reporting involves documenting methodological details, including allocation procedures, implementation barriers, and intervention fidelity. This not only reduces the risk of bias but also supports knowledge translation by enabling practitioners to understand how interventions were delivered and replicated in applied contexts ([Campbell et al., 2020](#); [Klamert et al., 2024](#)).

Pre-registration and Pre-analysis Plans

Pre-registration of hypotheses, study designs, and analysis plans is vital to prevent selective outcome reporting and post hoc rationalizations. Platforms for study registration encourage methodological rigor and accountability. Complementarily, Registered Reports offer peer-reviewed validation of methods prior to data collection, ensuring that findings are evaluated on the quality of the research design rather than the nature of the results ([Campbell et al., 2020](#)). These practices strengthen credibility and contribute to a culture of openness in sports science and are already accepted in numerous journals ([Abt et al., 2021](#); [Beauchamp, 2024](#); [Impellizzeri et al., 2019](#)). When drafting such reports, authors should follow the CONSORT ([Hopewell et al., 2025](#)) and SPIRIT guidelines ([Hróbjartsson et al., 2025](#)), which define the minimum recommended items for clinical trial protocols and provide a structured framework for reporting the rationale, objectives, design, randomization procedures, allocation concealment, blinding, outcomes, and analysis plan.

Feasible and Ethical Research Designs

Given the unique demands of sporting environments, researchers should prioritize designs that balance scientific rigor with ethical and logistical feasibility. Pilot and feasibility studies are strongly recommended for assessing recruitment strategies, intervention delivery, and adherence challenges before scaling to larger trials ([Arain et al., 2010](#); [Bowen et al., 2009](#); [El-Kotob & Giangregorio, 2018](#); [Lancaster, 2015](#); [Morgan et al., 2018](#)). Ethical considerations should remain central throughout the research process, ensuring that interventions are safe, scientifically justified, contextually appropriate, and compatible with the rights, welfare, and performance demands of athletes and participants. In line with updated ethical standards for sport and exercise science research, investigators should also consider informed consent, confidentiality, risk–benefit balance, participant autonomy, and the specific vulnerabilities that may arise in competitive or applied sport contexts ([Campbell et al., 2020](#); [Harriss et al., 2022](#)).

Pilot Testing and Intervention Fidelity

Pilot testing allows researchers to identify practical and methodological challenges early, refining study protocols and optimizing feasibility. Ensuring intervention fidelity is equally critical, as deviations in delivery can compromise internal validity. Monitoring and documenting fidelity at both the participant and instructor level helps maintain consistency, reduces variability, and allows accurate interpretation of outcomes ([El-Kotob & Giangregorio, 2018](#); [Klamert et al., 2024](#)).

By embracing transparent reporting, pre-registration, ethical and context-sensitive designs, and systematic pilot testing, researchers in sports science can produce findings that are both scientifically robust and practically relevant. When reporting pilot or feasibility trials, authors should follow the CONSORT extension for randomized pilot and feasibility studies, which provides specific guidance for describing feasibility objectives, recruitment, retention, adherence, intervention delivery, progression criteria, and the interpretation of findings before proceeding to a definitive trial ([Eldridge et al., 2016a, 2016b](#)). These strategies not only safeguard methodological integrity but also bridge the gap between controlled research environments and the complex realities of sport practice, ultimately enhancing the translation of evidence into applied performance and health settings ([Ely et al., 2021](#)).

As shown in Table 2, group-pooled analyses and person-specific approaches address different levels of inference and may provide complementary information in sports science research.

Table 2 - Checklist for Improving Randomization Practices in Sports Science Studies.

1. Planning and Design

- Define the purpose of randomization and justify its use in the study design.
- Select the randomized trial design appropriate to the research question and context (e.g., parallel-group, cluster-randomized, crossover, or stepped-wedge cluster-randomized), and then select an appropriate random allocation procedure (e.g., simple, block, stratified, or response-adaptive randomization).
- Pre-test feasibility with pilot or simulation studies to anticipate balance and adherence challenges.
- Clearly identify unit of randomization (individuals, teams, sessions) and ensure consistency across data collection.

2. Sequence Generation

- Use true randomization methods (e.g., computer-generated, randomizeR, RRApp, or OxMaR tools); avoid pseudo-randomization (e.g., alternating order or date of entry).
- Where appropriate for reproducibility, document the software, code, and seed value used to generate the allocation sequence.
- Pre-specify block sizes or stratification variables if applicable.
- Maintain unpredictability - do not allow researchers or coaches to foresee group allocation.

3. Allocation Concealment

- Ensure allocation concealment through sealed opaque envelopes, central randomization, or automated systems.
- Limit access to randomization lists to prevent selection bias or manipulation.
- Record who performed allocation and under what conditions.

4. Implementation and Monitoring

- Train research staff on randomization procedures to prevent procedural errors.
- Monitor adherence to allocation and record deviations or reassignments transparently.
- Plan for dropouts and protocol deviations, especially in elite athlete contexts.
- When conventional randomized trial structures are operationally difficult, consider whether an alternative randomized design, a pragmatic trial orientation, or a justified non-randomized design better addresses the research question and implementation constraints.

5. Transparency and Reporting

- Adhere to CONSORT guidelines (and extensions for crossover, cluster, or stepped-wedge designs).
- Clearly describe randomization method, concealment, implementation, and deviations in the methods section.
- Avoid claiming “randomization” unless true random allocation was used.
- Provide a flow diagram of participant allocation and retention.
- Where applicable, preregister relevant randomization procedures and analysis plans on an appropriate platform (e.g., ClinicalTrials.gov or OSF).

6. Ethical and Contextual Considerations

- Evaluate the ethical implications of withholding interventions in athlete populations.
 - Engage with coaches and athletes early to balance methodological rigor with practicality.
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- When cluster-level randomization remains feasible but simultaneous implementation is impractical, consider a stepped-wedge cluster-randomized design where appropriate. Bayesian methods may support inference or prespecified adaptive decision-making but should not be presented as a substitute for random allocation.
 - Where ethically justified and practically feasible, consider providing post-trial access to interventions shown to be beneficial.

7. Post-trial Reflection

- Assess and report baseline balance descriptively; avoid interpreting imbalance as ‘randomization failure’.
 - Reflect on lessons learned for future methodological improvement.
 - Where permitted by ethical, privacy, institutional, and data-sharing requirements, retain and, when appropriate, share randomization code and associated documentation.
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A further limitation concerns the extent to which group-pooled experimental and cross-sectional analyses can inform genuinely individualized practice. Conventional group-level analyses are primarily designed to estimate between-person differences and average associations across participants, but these effects do not necessarily characterize the processes operating within a given individual over time. As emphasized by ([Molenaar & Campbell, 2009](#)), population-level relations cannot automatically be assumed to apply at the individual level, particularly when substantial heterogeneity exists in temporal dynamics or responses to intervention. One study similarly highlighted the value of integrating nomothetic approaches, which identify general patterns across individuals, with idiographic approaches that characterize person-specific processes ([Beltz et al., 2016](#)). In sports science, this distinction is particularly relevant because athletes may differ substantially in training responses, recovery trajectories, physiological adaptation, and performance constraints. Accordingly, although group-based randomized and observational designs remain essential for estimating average effects and supporting causal inference at the population level, they may provide incomplete information about intraindividual dynamics and individualized decision-making. Greater integration of repeated-measures, intensive longitudinal, single-case, and person-specific analytical approaches may therefore complement group-level designs when the research objective is to understand individual adaptation or optimize individualized practice.

Conclusion and future directions

Sound randomization remains a cornerstone of rigorous experimental design because it strengthens internal validity and causal inference by reducing systematic allocation bias and, in expectation, improving comparability between study groups. However, randomization alone does not ensure that study findings are robust, credible, or broadly applicable across different populations and settings. External validity depends on additional factors, including the characteristics of the study population, eligibility criteria, intervention context, implementation conditions, study setting, and the extent to which the findings are applicable to the target population. This distinction is particularly important in sports science, where small and highly specialized samples, competition schedules, training constraints, and context-specific implementation may limit the generalizability of otherwise well-conducted randomized studies. Nonetheless, randomization is not without limitations. Challenges related to recruitment, protocol adherence, allocation concealment, participant dropout, and the implementation of randomized controlled trials in complex real-world environments highlight the need for methodological flexibility. Depending on the research question and study context, this may include adaptive randomized designs, pragmatic trial frameworks, Bayesian inferential methods, and carefully designed quasi-experimental approaches. Mendelian randomization should be considered separately as a complementary observational causal-inference method rather than as an alternative form of experimental randomization. The choice among these approaches should be guided by the assignment mechanism, required causal assumptions, feasibility, analytical requirements, and the intended interpretation of the resulting evidence.

Future methodological research in sport and exercise science should move beyond general recommendations and evaluate how different allocation and design strategies perform under the conditions that characterize applied sport research. Simulation studies could compare simple, block, stratified, and response-adaptive randomization in small and heterogeneous athlete samples, while further methodological work is needed to evaluate cluster-randomized and stepped-wedge designs in team environments characterized by small numbers of clusters, contamination, seasonal trends, and changing training exposures. Greater attention should also be directed toward the prevalence and consequences of inadequate allocation concealment, deviations from assigned interventions, and incomplete reporting of randomization procedures in sport-science trials. In addition, research is needed to identify design and analytical strategies that preserve causal interpretability while accommodating individualized training, practitioner decision-making, and the operational constraints of elite sport.

Advancing methodological quality in sports science therefore requires not only appropriate randomization procedures but also greater methodological literacy, transparent reporting, careful alignment between the research question and study design, and explicit recognition of the assumptions underlying alternative approaches. By integrating rigorous experimental principles with the practical realities of sport and exercise settings, researchers can strengthen the credibility, interpretability, and practical relevance of future evidence.

Declarations

Conflict of Interest Statement

The authors declare that they have no conflicts of interest, financial or otherwise, that could have influenced the conduct, interpretation, or reporting of this work. This is consistent with the declaration already included in the manuscript.

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Ethical Statement

Ethical approval was not required because this article is a narrative review based exclusively on previously published literature and did not involve the recruitment of human participants, collection of personal or sensitive data, interventions, or animal experimentation. Therefore, informed consent was not applicable.

Author Contributions (CRediT Taxonomy)

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