EDITORIAL

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RANDOMIZATION CHALLENGES AND SUGGESTED STUDY DESIGN IN AESTHETIC, PHARMACEUTICAL AND REGENERATIVE MEDICINE

It is ideal in medical research to perform experimental (interventional) clinical studies, such as RCTs, in all clinical investigations, nonetheless, quasi-experimental and observational research can be appropriate with careful consideration of study design and potential biases in aesthetic, pharmacological, and regenerative medicine clinical setups. Selection bias, protopathic bias, attrition bias, and performance bias are examples of sources of bias that can occur in RCTs, but there is a chance that their effects could be more pronounced in quasi-experimental and observational studies because these types of studies are frequently conducted without protocols defining standardised interventions, outcomes assessments, and data recording procedures.

The most popular design for evaluating the efficacy of healthcare therapies is the randomised controlled trial, or RCT. The adoption of a randomization technique, which, when carried out correctly, assures that no participant's allocation to one treatment or another can be predicted, is the primary advantage of the RCT. In the absence of randomised controlled trials (RCTs), healthcare practitioners and policy-makers rely on non-randomised studies to provide evidence of the effectiveness of healthcare interventions. However, there is controversy over the validity of non-randomised evidence, related to the existence and magnitude of selection bias. Nevertheless, several scenarios remain under which an RCT may be unnecessary, inappropriate, impossible or inadequate. Furthermore, there must be hundreds of examples of interventions for which RCTs would be possible but have not yet been carried out, leaving the medical community to rely on non-randomised evidence. Some experts even feel that the majority of aesthetic medicine treatments cannot be subjected to RCTs under “real-world” conditions. Aesthetic techniques are rarely standardised and an inherent variation in performance exists between aesthetic practitioners. This variation is further exacerbated by the frequent need for procedural modification in response to individual circumstances. The exclusion of cases secondary to these variations introduces serious biases and may ultimately result in underpowered studies. In addition, the learning curve associated with many complex procedures may place newer techniques at a disadvantage when compared to well-established interventions. Patients also often reject the randomization process because they do not wish their treatment to be decided by chance.

Based on extensive research, there is inconsistent use of nomenclature when describing non-randomised studies, especially in the aesthetic, pharmaceuticals and regenerative medicine fields. Some taxonomies may apply different definitions to the same study designs. A proper taxonomy of study designs is needed for aesthetic clinical trial intervention for better understanding in creating the study structure. It is perturbing for beginners to comprehend the research trial design without proper taxonomy as a guide for them to conduct aesthetic medicine clinical trials.

Some of the research designs suggested for aesthetic, pharmaceuticals and regenerative medicine fields are:

Non-randomised trial/quasi-experimental study: The investigator has control over the allocation of participants to groups, but does not attempt randomisation (e.g. patient or physician preference). Differs from a 'cohort study' in that the intention is experimental rather than observational.

Historical cohort study: A variation on the traditional cohort study where the outcome from a new intervention is established for participants studied in one period and compared with those who did not receive the intervention in a previous period, i.e. participants are not studied concurrently.

Concurrent cohort study: A follow-up study that compares outcomes between participants who have received an intervention and those who have not. Participants are studied during the same (concurrent) period either prospectively or, more commonly, retrospectively.

Case-control study: Participants with and without a given outcome are identified (cases and controls respectively) and exposure to a given intervention(s) between the two groups is compared.

Before-and-after study: A comparison of outcomes from study participants before and after an intervention is introduced. The before and after measurements may be made in the same participants or different samples.

Controlled before-and-after study: A follow-up study of participants who have received an intervention and those who have not, measuring the outcome variable both at baseline and after the intervention period, comparing either final values if the groups are comparable at baseline, or change scores.

Cross-sectional study: Examination of the relationship between disease and other variables of interest as they exist in a defined population at one particular time point.

Case series: Description of several cases of intervention and outcome (no comparison with a control group).

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