A tutorial on randomized study designs for lifestyle interventions

Unhealthy lifestyle behaviours such as an unhealthy diet, excessive energy intake, smoking, excessive alcohol use, physical inactivity and poor stress-coping behaviour can act as causal factors in the pathway of many diseases. There are various types of interventions available to address these risk factors and to help people adopt a healthier lifestyle in prevention of disease. Lifestyle interventions should undergo a thorough evaluation to assess their effectiveness before they can ben used in healthcare. The increased focus on unhealthy lifestyle behaviours has led to a strong demand for well-performed and high quality randomized controlled trials.

In a randomized controlled trial (RCT), individuals are randomly assigned to the intervention of interest or a control group. The RCT is widely used to evaluate new drugs, devices, surgery or other treatment modalities and can be considered the cornerstone of evidence-based medicine. Due to randomization confounders are equally distributed between groups and bias is avoided. However, randomization may not correctly account for patient preferences and non-adherence, which are important issues in lifestyle interventions and may threaten their validity.

Several aspects are important in the optimal design of a lifestyle intervention. Below we highlight a few:

Firstly, lifestyle interventions are often complex: multiple components of the intervention may interact. Additionally, the interventions are introduced at different organizational levels such as families, schools, or communities. Secondly, the underlying research question of a clinical trial is inextricably linked to its design and should be relevant and feasible to answer. Thirdly, evaluations of lifestyle interventions can be complicated by low recruitment, high rates of non-adherence and high loss to follow-up. It is therefore prudent to consider several aspects of the active and control interventions, such as the target group, control intervention, viability, duration of the intervention, and the enrolment. Fourthly, it is important to emphasize that participants in lifestyle interventions are actively involved in the intervention and can therefore not adequately be blinded. Lastly, offering a placebo lifestyle intervention is hardly possible, because any placebo intervention is likely to have some effect.

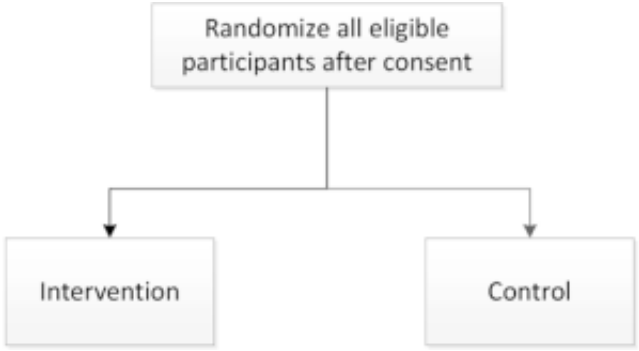

Fig. 1. Parallel randomized group design

Although RCTs are considered the cornerstone of evidence-based medicine, a straightforward parallel group randomized design (**Fig. 1**) will not necessarily lead to a high-quality study, and other randomized study designs may be a better choice such as a cross-over design (study interventions are given to each subject in successive periods), cluster design ('clusters' (groups) of individuals are randomized), or an RCT nested within a longitudinal cohort study (participants are first asked to participate in longitudinal observational cohort study, then the RCT).

For the majority of RCTs on lifestyle interventions, a pragmatic (realistic) approach is recommended, as it would be implemented in clinical practice compared with usual care as control. Special consideration should be given to the use of patient preferences in randomized trials of lifestyle interventions. Whether preference can lead to a better estimation of treatment effects when incorporated in the study design is still under debate.

With this paper we aimed to provide guidance in the choice of an optimal RCT design in future trials of lifestyle interventions. We show that difficult methodological choices have to be made to optimize the quality of an RCT evaluating the effectiveness of a lifestyle intervention. Evaluating lifestyle interventions calls for special considerations in designing the study, which are inextricably linked to the research question. We recommend considering alternatives to the conventionally used parallel group RCT. Our discussion of several types of RCTs suitable for evaluating lifestyle interventions, including their advantages and disadvantages, provides guidance in the choice of an optimal RCT design.

Publication

Randomized study designs for lifestyle interventions: a tutorial.
Younge JO, Kouwenhoven-Pasmooij TA, Freak-Poli R, Roos-Hesselink JW, Myriam Hunink MG
Int J Epidemiol. 2015 Sep 15