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Annals of Public Health and Research

Short Communication

Methodologies to Optimize the Internal Validity of a Diabetes Empowerment Self-Management Intervention Threatened by the Non-Adherence Issue

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Submitted: 07 November 2014

Accepted: 26 February 2015

Published: 28 February 2015

Keywords
- Diabetes
- Intervention
- Validity
- Non-adherence

Abstract

Non-compliance or non-adherence is one of potential threats to the internal validity of randomized controlled trials. The purpose of this study is to illustrate strategies to improve study validity threatened by non-adherence, which may shed light on methodology design and statistical analysis.

ABBREVIATIONS

RCT: Randomized Controlled Trail; DSME: Diabetes Self-Management Education; ITT: Intention-To-Treat.

INTRODUCTION

The RCT (Randomized Controlled Trial) studies provide the best and strongest evidence and could be used to evaluate the effectiveness or efficacy of the various interventions within a targeted population. When participants are allocated to different groups, however, the researchers have to be confronted with the probability that the participants failed to adhere to prescribed interventions or treatments. Non-compliance or non-adherence is one of potential threats to the internal validity of the clinical trials [1]. The purpose of this study is to describe the non-adherence, analyze the methodology to improve the validity of the RCT threatened by non-adherence, and evaluate the RCT validity through appropriate statistical method.

DESCRIPTION OF THE NON-ADHERENCE ISSUE

Various studies have been launched to examine the effectiveness of the Empowerment-based Diabetes Self-Management Education on patients with diabetes. Adherence is defined as "participants' active, voluntary, and collaborative involvement in a mutually acceptable self-management regimen to produce a therapeutic results" [2].

Self-management of diabetes is a complex and complicated process requiring strong self-discipline. Patients with have to overcome barriers within the context of daily life to obey the prescribed self-management regimen, including utilizing knowledge and skills, adopting the recommended behavior protocols, making appropriate decisions and adaptations, and consequently preventing complications [3]. Owing to the complexity of the self-management, participants are more likely to stray [4]. Even when participants are highly motivated to adhere, it is difficult for them to comply exactly with the recommended intervention. Non-adherence seems to be inevitable in RCT studies. The potential impact of the non-adherence is the dilution of the intervention effects or the potential loss of the study power. Therefore, it is of great importance to consider non-adherence issue and resort strategies to improve the inference.

RESULTS AND DISCUSSION

Methodologies to Optimize the Validity related to the Non-adherence Issue

Firstly, researchers are strongly recommended to maintain the integrity of the intervention. The less standardized intervention approach could result in the variability of the intervention received by the participants, creating the non-adherence to some extent and presenting a threat to the validity of the clinical trial [5]. The development of a protocol that includes the overview of the intervention, the sequences of the intervention activities, and the procedures of each domain of self-management education

could minimize the non-adherence rates proposed by the interveners and enhance the validity of the conclusion.

Another useful strategy to improve the validity is to develop some patient-centered interventions, taking full account of patients' individual needs, values, preferences, and situations. The patient-centered or individualized DSME (Diabetes Self-Management Education) means to cultivate participants to make informed decisions and encourage them to take responsibility of their behaviors and decisions [6]. A literature review showed that patient-centered approach was essential to facilitate the communication between the patients and nurses, motivate participants to engage in the self-management activity, and ultimately promote adherence [7].

Finally, including qualitative methods as supplementary part of RCT facilitates the interpretation the meaningfulness of the intervention. Even though the researchers value the significance of the quantifiable outcomes, the quantitative studies do have some limitations in answering "how" and "why" questions and providing the adequate evidence about the mechanisms of the interventions [8]. Qualitative study, on the other hand, could contribute substantially by unpacking the process box, exploring the impact of the intervention on the retention, and enhancing the meaningfulness of the clinical trial results [9]. Given the designed RCT in diabetes empowerment- based self- management interventions may yield changes in HbA1c or self-management behaviors, the qualitative study could be conducted to explore the intervention mechanisms and adherence facilitators perceived by the participants.

Evaluation of the Validity in RCT with respect to Non-adherence Issue

One useful strategy to deal with the potential non-adherence is to design an intervention program based on the Dose-Response Model. A Dose- Response Model could be used to estimate the probability of a specified change from exposure to a specified situation [10]. The advantage of incorporating the Dose-Response model in the clinical trial is that the researchers could treat non-adherence as continuous data and include the data as part of the intervention dosage [10]. Ultimately, the ability to detect the effectiveness of intervention could be more credible and reliable. However, the potential challenges for Dose-Response Model are the conceptualization of the dosage for intervention based on the theoretical framework [11]. In the Diabetes Empowerment Self- Management Intervention Programs, participants could be allocated into three groups: intensive DSME group (with more education sessions and shorter interval of follow-up, compared to the DSME group), DSME group, and usual care group. The effectiveness of the interventions could be addressed by the dose-response relationship between the attendance rate and the improvements of the outcomes.

One of the popular statistical methods to deal with the non-adherence is ITT (Intention-To-Treat) analysis approach. ITT approach is a strategy for the analysis that analyzes the patients according to the arms to which they were originally allocated, regardless of the actual intervention they have received or protocol violation [12]. ITT does not require observation of the adherence status or incorporate compliance into the analysis, therefore providing a "real life" scenario and yielding a conservative estimate of the intervention effects. Contrarily in a per-protocol analysis, only patients who complete the entire clinical trial according to the protocol are counted towards the final results, thereby undermining the power of analysis.

CONCLUSION

Though the validity of the RCT may be threatened by the non-compliance or non-adherence issue, RCT is still a gold standard for the clinical trial. Improving the internal validity of RCT studies is a demanding issue for researchers. This study may enable researchers to get a close insight about this methodological issue. Several possible strategies underpinned by theories or evidences were discussed to optimize the validity for future studies. The application of all these strategies needs rational operationalization of the intervention.

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Cite this article

Cheng L, Li X (2015) Methodologies to Optimize the Internal Validity of a Diabetes Empowerment Self- Management Intervention Threatened by the Non- Adherence Issue. Ann Public Health Res 2(2): 1016.