



THE ETHICAL ANALYSIS OF ADAPTATION OF RANDOMIZED CONTROLLED TRIAL APPROACH IN THE FIELD OF IMPACT EVALUATION FOR HUMANITARIAN PROJECTS

Sada Hussain Shah¹ⁱ,

Aijaz Ali Wassan²,

Abdul Hadi³

¹PhD, Sociology (Mixed Methods Research),
University of Sindh, Pakistan

²Professor, Department of Sociology,
University of Sindh, Pakistan

³Assistant Professor,
Department of Sociology,
Harran University, Turkey

Abstract:

Conducting and communicating research is a responsible intellectual job. A researcher would go analysing immense literature and would search for valid evidence. Prior to narrating an authentic statement. Correspondingly while selecting a method for study it is vital to opt for an approach that is ethically suitable in a defined context. While applied on a set of a populace, generally denoted to as a sample and/or universe. Therefore, social research would be a more laborious task. Hence, the social context is ever-changing in terms of time and space. Diverse methods of social research are being invented yearly. To compete with consistently changing social phenomena and needs of evidence. Operational research, evaluation, and screen monitoring are the most prominent approaches of modern social research. Hence, these naïve approaches of social research would undergo learning and adaptation. Community development projects and retrospective studies thereof are also being synthesized, with existing methods of social research. An identical practice is an adaptation of the Randomized Controlled Trial hereinafter (RCT) approach to conduct impact evaluations of humanitarian and development projects. Hitherto, RCT was being widely used by health researchers as a clinical research approach. Hence, an adaptation of this clinical research approach for field studies, particularly for the evaluation of humanitarian projects. Those are being implemented to provide survival support to vulnerable communities. It would require this approach to undergo some ethical adaptations. This research paper is developed to commence a wider literary discourse on requisite ethical adaptations for RCT to use in the evaluation of humanitarian projects. This research paper brings the findings from

ⁱ Correspondence: email rite2dr.sada@gmail.com

desk and field. To discuss key questions; where and how we can use RCT, and what ethical adaptations are necessary not to be forgone? This discourse is established on the usefulness of RCT, ethics of social research, ethics of evaluation, and humanitarian principles. The overarching purpose of this research paper is to facilitate the adaptation of RCT in the field of impact evaluation. While considering the ethical principles of the development sector and evaluation.

Keywords: randomized controlled trial, impact evaluation, humanitarian projects

1. Introduction

Findings and consecutive discussion presented herein are based on research literature and field experience. This research paper is developed after learning from a randomized controlled trial approach used to conduct an impact evaluation of a multiple intervention aid project in the Sindh province of Pakistan. Hence, the original research is too wide and multidimensional. Therefore, only one study theme and findings are being discussed here. Eventually, the aim of this particular research paper is to start a discussion on the ethical appropriateness of using RCT. To conduct impact evaluations of humanitarian projects. Those projects are largely being implemented to pave the way from recovery to development. In addition to the available literature on ethical consideration of RCT for impact evaluation studies. This research paper has also highlighted the real opinions of people in situ, where that particular project was implemented and evaluated. Only one objective and research question of the study is taken for discussion. The research question and methodology of study are set forth under.

2. Objective of Study

- To assay the difference in livelihoods and food security among case and control groups.

2.1 Research Question

- What is the situation of livelihoods and food security, as experienced by the community?

3. Methodology

The qualitative operational research method is applied during the study using the RCT approach. Operational research approaches are used to study the impact and results of a project, consortium, or organization (Wagner, 1982). The RCT is a robust method to examine the cause and effect relationship in intervention and outcome (Bhide et al., 2018).

3.1 Sampling Method

Under operational research, we often collect qualitative data from pre-known populations. Hence, the non-probability purposive sampling method was applied in the proposed study (Palys, 2008). Respondents under this study have certain criteria to be part of the review. Therefore, a sub-type of purposive sampling (criterion purposive sampling) was applied for the collection of data from individuals.

3.2 Data Collection Tools

Key Informant Interviews (KII) with government and project officials and In-depth Interviews (IDI) with project beneficiaries were conducted. As per the definition of interview by (Given, 2008), an interview helps the researcher to interpret the meaning of respondents as per their perspective. Focus Group Discussions (FGDs) with women of the community were also conducted prior to detailed interviews with specific cases. FGD is a good tool to collect information from a homogeneous group of people about the topic of their interest (Krueger, 1988).

3.3 Data Analysis

For analysis of qualitative data collected through different tools. The simple thematic analysis technique was used. As per (Maguire & Delahunt, 2017) simple thematic analysis is bringing all relevant material under the umbrella of each research question and/or theme and discuss for understanding. For desk review, the content analysis method was applied. As per (Carley, 1993) the content analysis helps to understand the logic of the text.

4. Literature Review

In the past few decades, our planet became prone to catastrophes. Natural and man-made disasters are being witnessed frequently. The global humanitarian overview for 2017 depicts initial funding requirements of \$22.2 billion to help 92.8 million people in need (OCHA, 2017). The world now has a population of 70.8 million forcibly displaced people (UNHCR, 2018).

These figures postulate the needs for food, shelter, and protection for the displaced. Consecutively immense humanitarian projects are being implemented to help vulnerable communities. Most of these projects would be extrapolated from humanitarian to development. Numerous evaluation studies are/were being conducted to document the results of these projects. A similar study was conducted in Pakistan. That was an impact evaluation of a humanitarian project. The project was technically considering under humanitarian and development nexus. Hence, Pakistan is one of the disaster-prone countries for two decades. As explained by (Swathi, 2015) Pakistan is facing frequent natural disasters for the past decade. That is causing internal migration and displacement of the population. Displaced people always face problems adjusting to the social life of the areas where they embark. Increasing population and food demands

are also exhausting natural resources and displacement continues. Changing population has a reciprocal relationship with changing environment. However, the other issue is gender mainstreaming. The content analysis of these findings would postulate the vulnerability of the populace and successive support. The analysis would still go down narrow to examine the vulnerability of the populace in categories of age and gender.

Profound literature suggests the lack of gender participation in humanitarian projects. Due to the differences of gender needs, men-decision makers fail to comply with considering women's needs for rescue (Mehta, 2007). Even while strategic planning of sustainability and resistance gender needs and gender potential is not considered (Syed and Gonzalez, 2014). Lack of women representation in disaster risk reduction institutions is causing gender-blind disaster risk reduction policy and planning. Post-colonial disaster risk reduction policymaking approach and weak institutions are responsible for poor policy-making (Cheema et al., 2016).

Establishing on needs of the population and context several support-projects are being implemented by humanitarian workers. Most of these smart projects implemented by different actors. Technically fall under three general categories; rescue, recovery, and development. Rescue and recovery phases are collectively described as a humanitarian phase. The projects those lead communities from the humanitarian to development phase are known as the developing humanitarian and development nexus. (BMZ, n.d.) transitional development assistance is to provide support to the vulnerable communities at the level of recovery. To help communities getting stronger and prepare for the development phase. Humanitarian projects are being implemented in the situation of disasters. Targeted populations are considered vulnerable; because, they need external support for survival. Recovery projects are known as humanitarian and development nexus project. Hence, these are supposed to pave the way from relief and recovery towards development. Development projects are being implemented at a time when the context is stable. The context and populations are considered stable when the populace has developed the capacity to survive on their own. Development projects are mostly focused on building the capacity of the communities to help themselves. Established on that if we examine the use of RCT approach to conducting impact evaluation. It is a randomized and controlled study conducted to explore the impacts of the intervention. Where the impact is being studied based on findings between case and control group. Hence, under humanitarian projects targeted populations are vulnerable. Therefore, it would not be ethical to deprive a group of people of aid. Merely for the purpose of studying the impacts of aid. However, under the recovery projects, RCT is being used in some cases. Hence, the literature on ethics of social research is demanding ethical adaptations for the use of RCT for impact evaluations of humanitarian projects. (Stolberg et al, 2005) their research paper 'Fundamentals of clinical research for radiologists' suggested that before conducting RCT researchers must have enough knowledge (equipose) about the effects of an intervention under study. It is important to consider research ethics during RCT. As discussed by (Ana et al., 2018), this is the responsibility of social-work researchers to explicit ethical values in their research work. Hence, the

domain of social research is very wide. Therefore, this discourse is specifically focused on published literature on ethics of evaluation. A paper was presented by (Sandra, 2007) at the University of Mexico. The paper describes; methodological work done by evaluators is incomplete until-unless it accords the ethical values. Being more focused, let us embark on our journey towards ethical considerations while conducting RCT. (Howard, 2014) under RCT case and control groups are chosen randomly among similar populations to measure the impact. (Anupam, 2012) RCT provides equal opportunity to the case and control group to be part of the trial. Inter alia; humanitarian work is deeply rooted in humanitarian and accountability principles. (FAO, n.d.) Accountability to Affected Populations hereinafter (AAP) is to ensure the dignity of affected populations. AAP is the inclusion of all beneficiaries in programming, regardless of colour, race, age, and gender. AAP is applicable at all levels of the project cycle; planning, implementation, monitoring, and evaluation. The most popular guide for the humanitarian sector (The Sphere Handbook, 2018), emphasizes on considering the principles of accountability, impartiality, transparency, and do no harm in aid-projects. These humanitarian principles are referred to as the Core Humanitarian Standard (CHS). Therefore, established on content analysis of RCT, CHS, and APP. It would be important to consider the suitability of RCT to conduct impact evaluations for relief and recovery projects. Because if we do not provide aid among a group of people for the purpose to study the retrospective impact of aid. It would be ethically fragile under humanitarian values. Therefore, being an evaluator for relief and recovery projects. It is important to know where and how we would use RCT. We have field experience in conducting RCT for an impact evaluation of recovery projects. Findings set forth would explain the conditions of case and control groups. These findings are against a single theme of study. Hence, under other themes of study, no fragile conditions of the control group were observed. Hence, every project theme doesn't require targeting vulnerable populace. Content analysis of the literature narrated above also demands precautionary use of RCT only for vulnerable groups/and situations. Other study themes like providing awareness were not targeting the vulnerability. The vulnerability was targeted specifically under project themes that were linked with distributions of aid packages. However, considering the current random behaviour of spread and cure of COVID-19. RCT may also undergo some technical modifications to sustain its status as the best clinical trial. Hence, RCT is an ancient research approach it was first used by James Lind in 1747 while curing patients of scurvy (Goldstein, 2018).

4. Results and Discussion

4.1 Theme-X Livelihoods and Food Security

Context analysis through FGDs and KIIs depicts that diseases among women, children, and livestock are increasing over the past six years. Crops and other labour opportunities are decreasing and inflation is increasing. The situation of food insecurity is increasing due to the loss of lands, crops, and cattle. Due to waterlogging and harsh weather vector-

borne diseases are also increased. Those have damaged the health of children and also have increased medical expenses. Heatwaves increase expenses on health and energy drinks and decrease income generation and labour options. In village life the custom of helping each-other is decreasing. Households often vend their livestock or take money on interest during hard days. Average households are living in poor conditions, no household is in a position to support others financially.

IDs with the case group found that during last year's extreme weather households took safety measures like using energy drinks and covering heads with a white cloth. In general majority of households changed their working hours and used a white cloth to avoid direct sun-stroke. Women were encouraged to participate in the marketing of harvest and cattle. Case group households were provided seeds, fertilizers, and training under project. Free seeds, fertilizers, and agriculture tools reduced the cost of production. Trained farmer groups could access the local market without the intervention of middlemen. Hence, households could save extra than customary earning. Vaccination for livestock reduced the mortality of domestic animals and also improved their health. Targeted households were blissful to receive aid and support. Henceforth, they were feeling improvement in their livelihoods. Hence, households did not take any loan. They could reserve plenty of cereals that they would be using for their food and for the next sowing. Therefore, targeted communities were feeling a sense of security for their livelihood and food.

IDs with the control group found that communities were relying on customary practices against heatwave. Such as: drinking lemonade and avoiding exposure to the extreme sun. Women do participate in livelihoods but at the level of production. Marketing is done by men and they keep income in their hands. Men are the decision-makers and responsible to bear the expenditures of the family. Sometimes they borrow money on interest to fulfil the needs of the household. In juxtapose to case group, control group households lent seeds and fertilizers on interest as often. Control group households were not aware of marketing. Hence, they vended their products at a low price. Control group households explained that they could hardly stock cereals for their food till the year. They will again borrow seeds on interest and the vicious cycle would continue. Hence, no casualty among livestock was found but their livestock was not vaccinated under the project. The juxtaposition of findings tells the clear story that the case group has improved their livelihood and food security as compared to the control group. Hence, it gives enough evidence for researchers to claim the impact of the project.

Based on learning from current RCT, conducted to observe the impacts of a humanitarian project. It could be said that RCT would require to adapt ethical corrections when used under humanitarian projects. However, communities in the control group were also equally affected by the disaster. This study was conducted amid of project and it proposed to continue equal support for all affectees thereafter. Henceforth, the findings of this study would support generating evidence around required ethical adaptations for RCT to conduct impact evaluations of humanitarian projects.

5. Conclusion

Community development projects, particularly, humanitarian projects are ethically sensitive. Either while being implemented or studied. RCT could be the best fit for clinical trials but when it comes to the field of impact evaluation. It would require some changes based on humanitarian principles. For development projects, those are implemented under stabilized context. RCT would not require major methodological changes. We can conduct RCT by dividing targeted beneficiaries into two groups. Group-1 receives development support in the early phase of the project, and group-2 would receive capacity building support a little later. Under humanitarian and transitional aid projects. Those have special agenda of relief and/or recovery. RCT would have ethical fragility in operation by dividing targeted beneficiaries into two groups. Where group-1 receives the aid and other await. This waiting for aid may have negative effects on vulnerable targeted beneficiaries. Therefore, if we would prefer to use RCT to conduct impact evaluations of humanitarian and/or transitional aid projects. We would require taking a random sample from an identical community as our control group. Rather dividing our intended beneficiaries into case and control groups. The findings of that identical control group may also serve the purpose of developing a baseline. Further, we can develop another project for that identical group established on findings. In case, it is not contextually possible to select an identical group as our control group. We would need to think of another suitable technique to conduct RCT under humanitarian principles. Further, it also depends on themes or sectors of humanitarian projects. The findings of this research work reflect only livelihoods and food security. There would be many other ways those need to be explored further to support the ethical adaptation of RCT in the field of impact evaluation particularly for humanitarian and transitional-aid projects. The core focus of this research paper is to support exploring nonfragile ethical ways to conduct impact evaluations using RCT under humanitarian principles.

Conflict of Interest Statement

The authors declare no conflicts of interests.

About the Authors

Dr. Sada Hussain Shah is PhD in Sociology (Mixed Methods Research) with hands-on experience in the fields of social research, social survey, monitoring, evaluation, and learning. He has been working with academia, UN and INGOs at national and international levels.

Dr. Aijaz Ali Wassan is professor and chairman for the department of Sociology, University of Sindh, Jamshoro, Pakistan.

Dr. Abdul Hadi is assistant professor for the department of Sociology, Harran University, Turkey.

References

- Bhide, A., Shah, RS., G. (2018). A simplified guide to randomized controlled trials. Nordic Federation of Societies of Obstetrics and Gynecology AOGS; 97, 380-387. doi: 10.1111/aogs.13309.
- BMZ Strategy Paper 6. (n.d.). Strategy on Transitional Development Assistance: Strengthening Resilience-Shaping Transition. Retrieved from <https://www.alnap.org/system/files/content/resource/files/main/strategiepapier335-06-2013.pdf>
- Carley, K. (1993). Coding Choices for Textual Analysis: A Comparison of Content Analysis and Map Analysis. *Sociological Methodology*, 23, 75-126.
- Cheema, A.R., Mehmood, A. & Imran, M. (2016). Learning from the past Analysis of disaster management structures, policies and institutions in Pakistan. *Disaster Prevention and Management*, 25, (4), 449 – 463. doi: <http://dx.doi.org/10.1108/DPM-10-2015-0243>.
- FAO in Emergencies. (n.d.). Guidance Note: Accountability to Affected Populations. Retrieved from http://www.fao.org/fileadmin/user_upload/emergencies/docs/Guidance%20Note_Accountability_Publi.pdf
- Given, L. M. (2008). Retrieved from The Sage Encyclopaedia of Qualitative Research.
- Goldstein. M. (2018, April 18). The history of randomized control trials: scurvy, poets and beer. Retrieved from <https://blogs.worldbank.org/impac evaluations/history-randomized-control-trials-scurvy-poets-and-beer#:~:text=Putting%20the%20idea%20into%20practice,is%20trying%20to%20cure%20scurvy.&text=This%20trial%20was%20actually%20double,differences%20a cross%20treatment%20and%20control>.
- Harald. S., Geoffrey. N., Isabelle. T. (2005). Randomized Controlled Trials. *American journal of roentgenology*. 183, (6), 1539-1544. doi: 183. 1539-44. 10.2214/ajr.183.6.01831539.
- Krueger, R. A. (1988). *Focus Groups: A practical guide for applied research*. Sage, UK.
- Maguire, M., & Delahunt, B. (2017). Doing a Thematic Analysis: A Practical, Step-by-Step Guide for Learning and Teaching Scholars: *AISHE-J*, 8, (3), 3351-3361. doi: <http://ojs.aishe.org/index.php/aishe-j/article/view/335>.
- Mathison, S. (2007). Ethical Issues in Evaluation. International Symposium on Evaluation, National Autonomous University of Mexico. Retrieved from https://www.academia.edu/7116611/Ethics_in_Evaluation
- Mehta, M. (2007). *Gender Matters Lessons for Disaster Risk Reduction in South Asia*. Kathmandu: International Centre for Integrated Mountain Development.
- OCHA. (2017). *Global Humanitarian Review for 2018*.
- Palys, T. (2008). Purposive sampling. *The Sage Encyclopedia of Qualitative Research Methods*, (2), 697-698.

- Prakash, A., Acharya, A. S., & Nigam, A. (2012). Indian Journal of Medical Specialties: 3 (2), 198-202.
- Sobočan, A. M., Bertotti, T., Strom G. K. (2018). Ethical considerations in social work research. European Journal of Social Work: European Journal of Social Work: 2-14. doi: 10.1080/13691457.2018.1544117
- Stolberg, H. O., Norman, G., Trop, I. (2004). Fundamentals of Clinical Research for Radiologists. AJR: 183. 1539-1544.
- Swath, J. M. (2015). Monographic issue the profile of disaster risk reduction in Pakistan and institutional response. 2, (1), 1-55.
- Syed, A. S. & Gonszalez P. A. (2014). Flood disaster profile of Pakistan: A review. Science Journal of Public Health. 2, (3), 144-149. doi: 10.11648/j.sjph.20140203.11.
- The Sphere Handbook (2018). Humanitarian Charter and Minimum Standards in Humanitarian Response. Retrieved from <https://spherestandards.org/wp-content/uploads/Sphere-Handbook-2018-EN.pdf>
- UNHCR. (2018). Global Trends; Forced Displacement in 2018.
- Wagner, H. M. (1982). Principles of Operations Research, with Applications to Management Decisions. New Delhi: Prentice Hall of India.
- White, H., Sabarwal, S., & Hoop, T. (2014). Randomized Controlled Trials. UNICEF Office of Research, Florence. Retrieved from https://www.unicef-irc.org/publications/pdf/brief_7_randomized_controlled_trials_eng.pdf

Creative Commons licensing terms

Author(s) will retain the copyright of their published articles agreeing that a Creative Commons Attribution 4.0 International License (CC BY 4.0) terms will be applied to their work. Under the terms of this license, no permission is required from the author(s) or publisher for members of the community to copy, distribute, transmit or adapt the article content, providing a proper, prominent and unambiguous attribution to the authors in a manner that makes clear that the materials are being reused under permission of a Creative Commons License. Views, opinions and conclusions expressed in this research article are views, opinions and conclusions of the author(s). Open Access Publishing Group and European Journal of Social Sciences Studies shall not be responsible or answerable for any loss, damage or liability caused in relation to/arising out of conflicts of interest, copyright violations and inappropriate or inaccurate use of any kind content related or integrated into the research work. All the published works are meeting the Open Access Publishing requirements and can be freely accessed, shared, modified, distributed and used in educational, commercial and non-commercial purposes under a [Creative Commons Attribution 4.0 International License \(CC BY 4.0\)](https://creativecommons.org/licenses/by/4.0/)