Advantage of Clinical Research in The Treatment of Different Diseases

Abstract

Clinical research is usually conducted on a consort of people, while clinical research's primary goal is to assess different novel treatments, including new drugs, new devices, etc.; to figure out if the treatment is secure, effective, or harmful for patients. Clinical research is mostly conducted to treat different diseases, including; hypertension, diabetes, CVD, neurological disease, stress disorders, migraine, and other diseases. This study aims to highlight the advantage of clinical research in the treatment of different diseases. For this reason, this study has searched the existing literature and the strategies employed in clinical research from recent years, to deliver a recent insight into the advantage of clinical research in the treatment of various diseases. This study has not included those researches that had only discussed the drawbacks of clinical research, as per this study's main objective.

Consequently, different studies conducted clinical researches for the treatment of various diseases. For the implementation of any novel and advanced treatment, clinical researches are most important for the detection and occurrence of specific side effects and to evaluate the efficacy of the treatment to assess if the treatment is more effective than the existing treatment or not. In this modern age, considering the advancement of technology, researches are mostly relying on in silico models. This study aims to highlight the value of clinical research for data collection and novel treatment implementation.

KEYWORDS: Clinical research, treatment, diseases, CVD, hypertension, diabetes, in silico, migraine.

Introduction

The predominant aim of clinical research is to assess the efficacy of the treatment and various side effects on patient's health. Clinical research is classified as; observational studies and clinical trials (Andersen et al., 2016).

Ioannidis (2016) defined clinical research as an investigation that answers the queries on treatment, prevention, diagnosis, and prognosis of diseases or novel approaches for the improvement and maintenance of health. Clinical trials majorly answer the concerned questions regarding new treatments and approaches; however, pertinent evidence are provided by observational studies. Till date, about one million from clinical trials have been published, but most of them did not mention the importance of clinical research in the current era of medication. Ioannidis had discussed the crucial characteristics of applicable clinical research, namely; problem base, context placement and information gain, pragmatism, patient-centeredness, value for money, feasibility, transparency or trust, etc.

The American College of Physicians and the American Academy of Family Physicians has demonstrated clinical research for the pharmacologic treatment of hypertension in adults of sixty or sixty above the age of years. And that clinical research has revealed most of the patients with 150 mm Hg or greater had responded positively to the administered anti-hypertensive drugs and only a few side effects were reported as compared tow BP patients. And, also has suggested confirming exact BP measurements before commencing or substituting antihypertensive drugs (Qaseem et al., 2017).

Lopes et al. (2018) had shown the bifurcation between preclinical and clinical studies concerning stem cell type, origin, and delivery techniques. In preclinical and clinical research review; he concluded that rather than amputation stem cell therapy is an effective way of treating diabetic foot ulcer; and demonstrated the current use of stem cell therapy as an alternative of amputation in diabetic patients.

This study has aimed to specify the role of clinical research in the treatment, and novel approaches' efficacy and side effects, of various diseases. There is an essential need to magnify the importance and advantage of clinical research for the implementation of new treatments; hence, this study intends to culminate clinical research in recent times used in the treatment of different diseases.

Literature Review

Elfil & Negida (2017) has suggested specific sampling methods in clinical research. Moreover, in clinical research, Elfil & Negida illustrated that a group of people sharing typical characteristics is defined as a population. While working on a particular disease, it is difficult to collect data from the whole population, like diabetes, it is unable to collect data from every diabetic patient. Accordingly, the entire population is not included in any clinical research; instead, part of the population is used in clinical research as a sample population, the whole population is termed as the target population, and the selected group of people are termed as the study population; for example, if a study that is conducted on about thousand HIV patients in such a case those thousand HIV patients are the study population as well as the representative of the remaining patients. The study population must represent the target population, and the

selection of a particular study population is often termed as a sampling method or study design (Elfil & Negida, 2017).

Solomkin et al. (2017) had escorted clinical research to assess the effectiveness and safety of eravacycline in contrast with ertapenem in patients suffering from complicated intra-abdominal infections (cIAIs). Consequently, eravacysline has shown equivalence to ertapenem in patients with cIAI.

Gross et al. (2019) had employed crossover clinical research to determine the efficacy and risk factors of exogenous ketone bodies to treat migraine. The study was conducted on 45 participants of about 18 and 65 years of age at Switzerland's headache clinics. Following a four week baseline period, patients were randomly administered to trial arms and encountered beta-HB mineral salt or placebo for twelve weeks. After that, a four-week wash-out was administered, and then a second baseline period, and at last, a second 12-week intervention with alternative treatment. The main results were the mean change from baseline in the number of migraine days throughout the last four weeks of intervention compared to placebo. Gross et al. evaluated the efficacy of beta-HB mineral salt in treating migraine with the employment of a single, centered, randomized, placebo-controlled double-blind crossover trial (Gross et al., 2019).

Lopes et al. (2018) had demonstrated the clinical and preclinical studies for the stem cell therapy of diabetic foot ulcers (DFU) also had evaluated stem cell therapy as effective in treating DFU. Abrahamyan et al. (2016) had suggested different clinical study designs in rare diseases and had provided a guideline for researchers in selecting alternative study designs for rare diseases. Other frameworks of clinical studies are used for the assessment of different treatments of various studies.

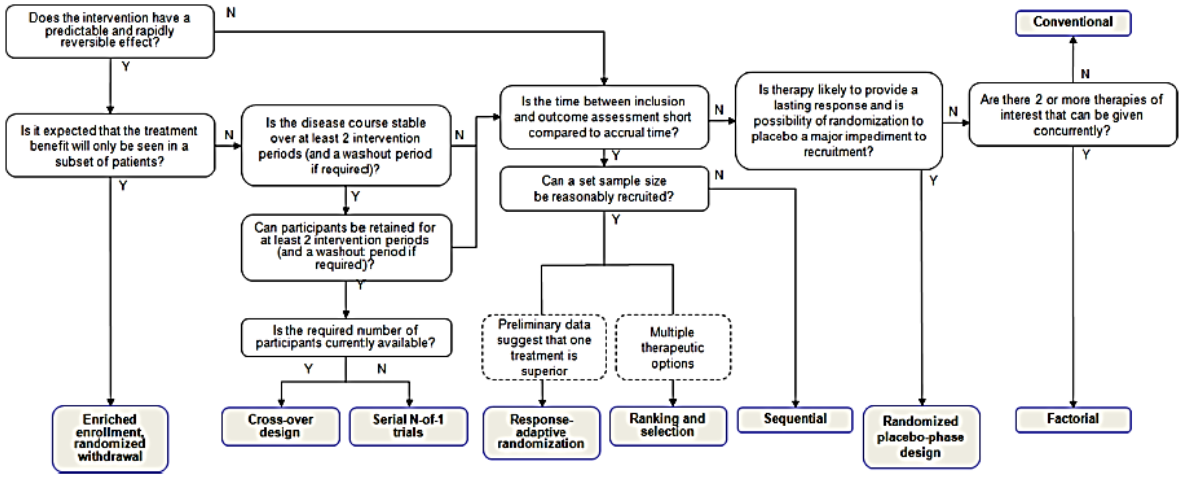

Figure 1: Framework of Alternative clinical study designs (Abrahamyan et al., 2016).

Meske et al. (2018) exemplified the effectiveness of opioids in the treatment of chronic non-cancer pain via a three months randomized controlled trial; the participants of this study were titrated with an elevated dose of the drug and then randomized to a high dose group, a low dose group, or the placebo group (Meske et al., 2018).

Clinical research is mostly used to assess the treatment of different diseases and had brought immense advantage to the treatment process. For the most part, clinical studies have helped evaluate and efficacy and need new treatment for various diseases. This study has bestowed an insight into the recent clinical trials.

Methodology

There are different clinical research design types, but clinical research is categorized into observational studies and clinical trials, and clinical trials are further of six kinds. This study has selectively demonstrated the assessment of treatments that had employed any of the six types of clinical trials. Moreover, the development of statistical and computational potential has assisted the clinical research concerning the sample selection.

This study's methodology is based on vast literature from recent five years to provide the latest insight concerning the advantage of clinical research in treating different diseases.

Data Sources

Data sources include the published literature from 2015-2020. The publications of specific ethical journals are used for data collection.

Data Recognition & Selection

Only those studies are included in this insight that had found clinical research a successful tool in inventing new treatments for specific diseases. Most of the studies selected have highlighted the effectiveness of clinical research in assessing psychotherapeutic, pharmacological, and physiological treatments of specific disorders.

Exclusion Criteria

This study aims to discuss the advantages of clinical research only; for this purpose, studies that are not recent and discussed the drawbacks of clinical research in the medical field are excluded in this study.

Future Perspective

For future perspective, this study has suggested specific clinical trials that can be used by the researchers in developing treatment strategies for certain specific disorders.

Limitations

The study is restricted to a time of recent five years and has only discussed treatments of few diseases. In order to deepen the insight concerning the advantages of clinical research, more treatments should be added, and the study should apart from any time restriction.

Results and Discussion

Abrahamyan et al. (2016) had suggested some alternative designs for clinical trials in rare diseases. The alternative designs include; cross-over trial design, N-of-1 trials, randomized placebo phase design, enriched enrollment- randomized withdrawal design, adaptive designs, and combination of designs.

Cross-over trials are comprised of a comparison of two or more treatments by assigning each partaker to all contrasted treatments in a randomly determined order. Gross et al. (2019) presented a single-centre, randomised, double-blind, placebo-controlled, crossover trial to assess whether beta-HB in mineral salt form reduces migraine frequency-related symptoms or not. Gross et al. had demonstrated three main advantages of cross-over trials in his studies. Firstly, a crossover design immensely enhances the statistical potential. This aspect is advantageous in disparate diseases like migraine and requires less study population to assess a given effect. Secondly, crossover designs provide the possibility of an IMP trial, which mostly elevates

consent, motivation, and participation rates. Finally, Gross et al. concluded that a crossover trial permits incorporating a second baseline period, which had controlled any possible seasonal effect on migraine frequency.

Abrahamyan et al. define N-of-1 studies as randomized clinical trials that seek the principles of crossover randomized controlled trials (RCTs) to the study of a single subject. Golden et al. (2020) applied self-directed, mobile N-of-1 studies to assess caffeine and L-theanine effects on cognitive performance. Golden et al. had used a statistical model that describes various variables, bias, and learning effects. The study was considered to be apposite to individual participants that need a positive life change and was also relevant to clinicians and researchers captivated in exploring N-of-1 studies. Golden et al. concluded that the cognitive process could be enhanced by acquiring knowledge about self-investigation and behavior change and the source of digital study termination.

Randomized placebo- phase design (RPPD)is used to refine the acceptability of entering a trial by reducing the time of placebo exposure. RPPD is originated for treatments with an enduring response and is not appropriate for crossover designs (Abrahamyan et al., 2016). Weinreb et al. (2018) had assessed the effect of oral memantine for the treatment of glaucoma by using a randomized placebo-controlled phase design. Weinreb et al. concluded that RPPD had imparted valuable outlooks concerning the study population selection and risk factors. Such studies also suggested the various methods for further developing neuroprotective agents in glaucoma; however, the study did not meet the primary endpoint.

Enriched Enrollment, Randomized Withdrawal design intends to involve “enrichment strategies” at the study design phase, selecting a patient subgroup. The evaluation of a therapeutic effect is more probable than the whole disease population. Meske et al. (2018) reviewed the efficacy of

opioids versus placebo in chronic pain by employing enriched enrollment withdrawal trials. Meske et al., with these clinical trials, concluded that opioid analgesics are effective in producing effect for at least three months and are potent for the treatment of chronic pain and other chronic diseases.

A few clinical designs allow researchers to apply collected data and actively adapt study design without impairing validity or integrity. Such “adaptive designs” mainly reduces the size of study population and preserve statistical validity. Cummings et al. (2019) employed adaptive for Alzheimer’s disease (AD) drug development pipeline. The word “pipeline” had used to classify agents in early, middle, and late-stage trials. According to Cummings et al., differences were found in several agents, and the drug development program for AD was stopped. However, some of the programs were victorious in drug-placebo differences in phase 2 and were promoting.

A combination of designs that are usually used in clinical research is a combination of several designs that complement each other in rare disease research. In such studies, two or more than two auspicious treatments are selected and compared in sequential trials with pre-set stopping criteria. Merz et al. (2019) assessed a combination of clinical research designs for the treatment of posttraumatic stress disorder. Merz et al. concluded that no treatment was superior at the end of treatment. However, psychotherapeutic treatments had demonstrated heightened benefit than pharmacological treatments at the last follow-up. In his study, psychotherapeutic and pharmacological treatments were used as combination designs (Abrahamyan et al., 2016; Cummings et al., 2019; Golden et al., 2020; Gross et al., 2019; Merz et al., 2019; Meske et al., 2018; Weinreb et al., 2018).

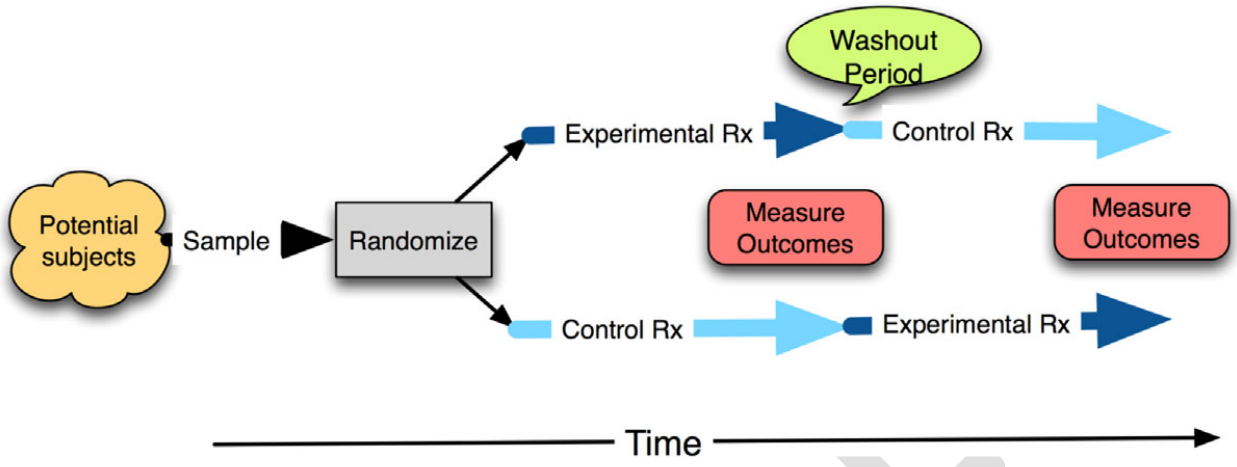

Figure 2: A flow work of Crossover Trials in clinical research (Abrahamyan et al., 2016).

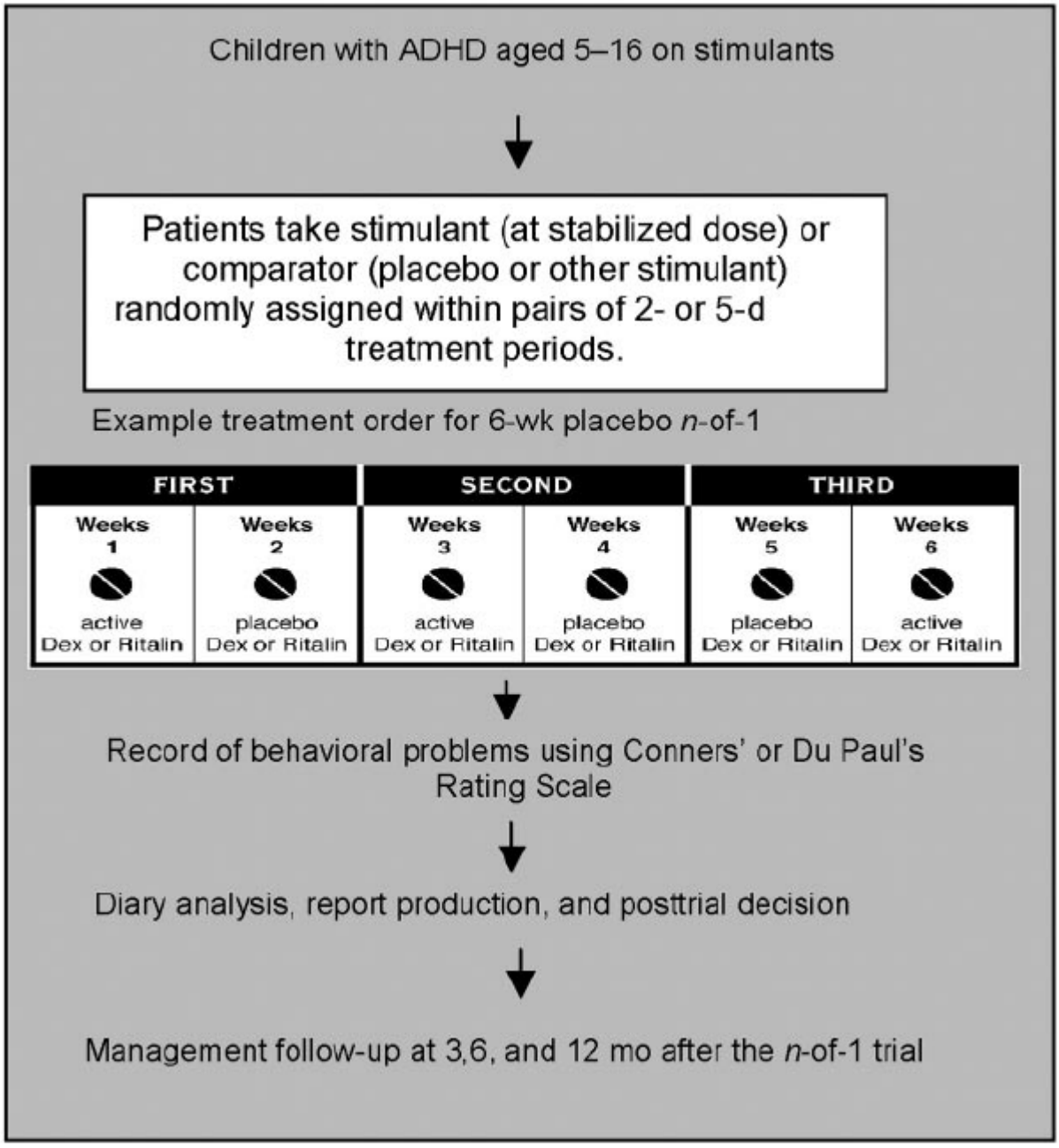

Figure 3: Nikles (2006) had demonstrated an N-of-1 trial SERVICE IN CLINICAL PRACTICE and assessed the efficacy of stimulants for attention deficit hyperactivity disorder (ADHD).

The different observational and clinical trials used in clinical research are mostly found to evaluate the treatment process of certain diseases, including migraine, glaucoma, ADHD, Alzheimer's disease (AD), etc. On the whole, it could be said that clinical researches are found to assess the efficacy and risk factors of specific psychotherapeutic and pharmacological treatments. As per the main aim of this study, different clinical trials are demonstrated to highlight the advantage of clinical research in the treatment of various diseases. Moreover, any clinical research's main theme remains the same, i.e., a particular study population representing the whole population is selected first. The treatment's time is decided, and specific statistical analysis tools are applied for the final evaluation of clinical research. Overall, aclinical research doesn't need to be only employed to evaluate the efficacy of treatment. Moreover, it is also used to figure out if the treatment is more beneficial than the existing therapies or not.

Conclusion

Nowadays, clinical research is mostly neglected due to the use of in silico techniques for data collection. However, clinical research is of immense importance for collecting data assessing new therapies and their risk factors. This study has delivered a vast outlook on the advantages of clinical research in treating different diseases. Researchers adopt different designs of clinical research for assessing the efficacy of particular diseases. However, to achieve maximum benefits from any clinical research, researchers must be cautious about the applicability, advantages, and limitations of the selected study design.

Moreover, statistical and computational advancements enabled the assessment of the treatment efficacy of heterogeneous, genetic, psychological, and physiological disorders. This study has

demonstrated the treatment efficacy assessment of stress disorders, migraine, glaucoma, Alzheimer's disease, and use of opioids. This study has aimed to highlight the advantage of different clinical research protocols because, these days, not much literature exists about the benefits of clinical research. However, most of the literature found is usually about the failures of specific study designs. For this purpose, this study has provided insight concerning the advantages of clinical research in treating different diseases. Still, much work is required to heighten the role of clinical research in assessing other treatments. This study has only discussed the literature from the recent five years and has also discussed a few diseases' study designs.

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