

Treatment be considered in clinical trials nursing essay

[Health & Medicine](#), [Nursing](#)



taylors-university-logo. jpgShould The Patients' Perspective of Treatment be Considered in Clinical Trials? Student name: NG SHU HUI Student ID :

0303797 Tutor : Ms ESMEE YEE SIEW MEI Word count:

1418 Introduction Clinical trials, according to National Cancer Institute (2010), are researches and studies on prevention and treatment of a particular disease that involve human. The main purpose of clinical trials is to test the safety and efficacy of new drug, medical instrument or treatment. It can be a new route of administration of a marketed drug too. Since it involve human, it is strictly regulated to benefit volunteers and study participants so that their safety is protected. There are two types of studies under clinical trials, the interventional studies and the observational studies. Interventional study involves the specific alteration of therapeutic or diagnosis options among subjects, which can be randomly or not randomly assigned by investigator (Clinical trials. gov 2012). Observational study is biomedical research on human being that outcome of interventions are being observed and accessed compared to a controlled group (Clinical trials. gov 2012). Results or outcome measures of clinical studies are differing with the disease being studied. However, there are few concerns regarding the patient's view and perspective of treatment in the study. As patients are the subjects of the research, their point of view is important to be considered into clinical research study so as a respect of patient right and improvement of research outcome. A brief introduction to clinical trials According to National Institute of Health (2012), clinical trials are studies conducted to test the safety and efficacy of new drug or treatment by measurements. Clinical trials can be start 30 days after Investigational New Drug (IND) application (FDA 2011).

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There are four main phases in the study, namely phase I, II, III and IV (Chow and Shao 2002). In phase I studies, healthy volunteers will be the subject, except in the drugs with high toxicity, for example anticancer drugs, patient of the disease will be the study subject. At first single ascending dose will be given, followed by multiple doses to test the safety of the drug (Scott 2007). In this phase, pharmacokinetics and pharmacodynamics of the drug will be accessed as well as safe dose and dose frequency for the use of phase II studies (Eller 2001). Phase II studies is the study that first included ill patients with particular disease, to test the efficacy of the drug (Scott 2007). In other words, it is to test if the drug helps to cure disease. Usually the design of the study is double-blind to avoid bias (Eller 2001). In the double-blind trial, neither researcher nor patient knows the mode of treatment, either placebo treatment or standard treatment with active pharmaceutical ingredient (Bratman 2004). The later part in the phase, known as phase IIb, specify the best dose and dose range, as well as the bioavailability for different formulation and dosage form (Eller 2001). Short term side effects and associated risks with the drug will be determined as well in this phase. Researchers study and analyse the data from phase I and phase II before continue phase III studies. Phase III study is conformational study, which confirm the safety and effectiveness of the new drug or treatment (Scott 2007). Besides, special population such as elderly, children, pregnant women and patients with hepatic or renal impaired will be included in the phase (Eller 2001). The last phase, phase IV is an additional phase after drug is manufactured to make market-oriented-comparison, for example, cost-effectiveness and comparison with previously marketed drug (Chow and

Shao 2002). Besides, phase IV study includes access of patient's quality of life (QoL) and chances for additional indications. Patient's perspective and clinical trials Patient is an essential element in clinical studies as the results and outcomes are based on patients' condition via indication instruments such as glucose concentration in blood, ECG, tumor response, muscle mass et cetera, depending on the patient's illness and disease. The scores and scales from these monitoring machines will then be compiled and analyzed by researchers. However, researcher should not depend merely on the instruments' scores as the outcome of the studies. Patient's feedback and perspective is as well important because they are the one who receive treatment, who if not patient to evaluate the effectiveness of the treatment? In a recent clinical research done by Portenoy et al (2012), Nabiximols, a cannabinoid novel drug formulation is tested for its effect on relieving pain of advanced cancer patients. In the study, Portenoy et al use Interactive Voice Response System (IVRS) to communicate with patient. Patient is asked to answer questions regarding to the pain they feel each day during the studies, based on visual analogue scale (VAS) (Mckechnie 1993; Chapman 1985), which the intensity of pain is measured on a scale of 1 to 10. The scale is used as primary outcome measure, but other measures are used as well in the study. They are categorized as patient-reported outcome measures (PROMs), such as sets of quality of life questionnaires. In the study, EORTC quality of life and Patient Assessment of Constipation quality of life questionnaires are chosen as secondary outcome (Portenoy et al 2012). In other words, patients' feelings towards treatment are reflected to researcher as a reference of treatment effectiveness. So, what is quality of

life? Based on the definition given by World Health Organization, quality of life is " individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns."(WHO 1997) There are different types of quality of life questionnaires available from different organization such as World Health Organization (WHO) (Sexena et al 2001), European Organization for Research and Treatment of Cancer (EORTC) (Urdaniz et al 2008), and Short Form health survey 36 (Ware 2012). Survey questions vary from physical health, mental health, general health and well being, social function and vitality, depending on the patient's disease and treatment received (Ware 2012). Why are patient-reported outcome measures important? This can be answered using the result of the study conducted by Slevin et al in 1988. The study compared questionnaires about quality of life, anxiety and depression completed by both doctor and patient simultaneously; and the result had proved that doctor cannot precisely know the patient feelings, thus cannot determine the quality of life (Slevin et al 1988). Slevin et al concluded that patients should measure their quality of life as they know the feelings better. This inferred the importance of patient-reported outcome measures in clinical research and care of patient. Next, another major reason why should patients' view of treatment be considered in clinical trials is its ability to improve patients' compliance. Patients' compliance can be defined as the willingness of patient to follow doctor's advice on treatment and complete it (Aronson 2007). How can it help with patient compliance? It is a simple theory. If patient's opinions are to be listened and considered, they will feel respected and able to contribute to

medical science as well as future patient, thus they will follow full course of treatment and increase compliance. It is an easy approach, just by a better relationship with patient due to respect and communication. Compared to many suggested ways to increase compliance such as the measure of compliance by tablet count, therapeutic drug assays in blood or urine et cetera (Pullar et al 1989). Besides, Austin Regional Clinic, TX (1994) suggested that patient education and clear instruction able to help in patient compliance problems. This is one of the major concerns in research because poor compliance may be an obstacle in clinical trials as it can researcher misjudge drug's efficacy and draw a negative conclusion (Schechtman and Gordon 1994). Conclusion Clinical trial and study is an important process in drug development of drug and medical instrument in order to treat patient who are suffering from diseases. Some participating patient feels the trial is a hope for a cure in their desperation (Ellis 2000). Unlike pre-clinical in-vivo studies, clinical trial involve human who is able to express feelings and opinion. It is immoral to view patient as a subject to study without consider their opinion and perspective of the treatment at the first place. Moreover, there are advantages in taking patient perspective and feedbacks into consideration; improve patient's quality of life and their illness as well as compliance, thus better and accurate result can be obtain. By then accident such as Thalidomide incident can be avoid. Also, good clinical practice should be apply besides consider patient perspective to achieve the aim of clinical study, that is, to prove the effectiveness and safety of drug in human body.