**TREATMENT EFFECTIVENESS OF OUTPATIENT PSYCHOTHERAPY**

**FOR NON-PSYCHOTIC DEPRESSIVE DISORDERS**

**Project Acronym or Short Study Title: Psychotherapy Effectiveness Evaluation**

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# Protocol Synopsis

With the rapid pace of life and high pressure of work, mental health problems have attracted people’s more attention nowadays. Diseases like recurrent depressive disorders happen to people from all walks of life, among various age groups. As only using drug treatment for recurrent depressive disorder is not sufficient to meet the increasing need of relieving more severe mental health problems, this research emphasizes the role of outpatient psychotherapy in mental health service system for non-psychotic mental disorders. Prior research mostly either focused on the comparison of effectiveness between drug treatment and outpatient psychotherapy or evaluated the outpatient psychotherapy from the perspective of therapists. Less study employs the patients’ lens with individual differences to assess the impact of treatment sessions in the long run. This study seeks to identify an effective pattern of outpatient psychotherapy, based on a longitudinal encounter data of recurrent depressive disorder patients in multiple treatment centers. The research is designed to assess the success or failure of the current outpatient psychotherapy, using the data from both the self-report questionnaire surveys and the electronic health record (EHR). The research results are expected to have implications for policy and decision makers to build effective service model within health care systems, so as to achieve a successful service management.

# Background & Rationale

**Need -** Recurrent depressive disorder (current episode severe without psychotic symptoms), according to the ICD 10 version, refers to a disorder characterized by repeated episodes of depression, the current episode being severe without psychotic symptoms, as in code F32.2, and without any history of mania. As this non-acute, recurrent depression negatively influences people to different degree in many aspects of life, it is necessary to evaluate whether the outpatient psychotherapy will make patients get better, how it works, and what treatment methods take effect.

**Significance of patients’ feel for psychotherapy sessions -** The research design will be concerned with the evaluations of patients on treatment sessions, that is, to assess the quality of outpatient psychotherapy sessions from the perspective of patients, rather than a single lens from the therapists themselves. This study will adopt a revised session evaluation questionnaire to assess the role of treatment sessions (Stiles et al., 2002).

**Challenges to psychotherapy evaluation** - On the one hand, there might exist response bias when using questionnaire survey to find out how patients evaluate the outpatient psychotherapy. On the other hand, in the statistical analysis of the longitudinal encounter data, there could be censored data due to the lost of follow up in hospitals or treatment centers. Therefore, employing a survival analysis can deal with these censored data.

# Objectives

The main purpose of this research is to assess the effectiveness of outpatient psychotherapy so as to further specify the characteristics of patients and the factors involving in the service patterns. This study is concentrated on the treatment evaluation of outpatient psychotherapy, including evaluation of both the outcome and the process of changes among patients. It involves patients, family members, therapists and also the mental health service centers. Patients’ expectation and evaluation for the treatment sessions are considered to analyze the mechanism of changes.

The encounter data extracted from the patient’s electronic health records is huge and difficult to process, and loss of data at some time point might lead to analysis results that are not justifiable. Therefore, this research seeks to answer the cost-effect question through using the dose-effect model. It employs the statistical method of survival analysis to demonstrate whether the outpatient psychotherapy is effective or not. The research aims to define the mechanism between treatment and outcomes, in order to shed light on treatment outcome management and service model selection.

# Major Research Hypothesis and Associated Research Questions

What are the relationship between the number of sessions and the psychotherapy treatment effectiveness? Through investigating the mechanism of symptom changes among the patients, there could be some mediating variables between the relationship of treatment and outcomes.

How many percentage of the patients get better after their treatment sessions? The survival analysis in dose-effect design could indicate the effectiveness of outpatient psychotherapy. The dose-effect analysis will be majorly focused on the survival event of patients’ getting better.

Is the patients’ expectation to get better after treatment related to their session evaluation? Data collected via the questionnaires will be analyzed using correlation analysis and structural equation models to validate the hypothesized linkage between these two variables and their respective dimensions; other possible mediators or moderators are not excluded.

# Study Approach, Design

**DESIGN**

The patients’ symptom improvement and changes result from outpatient psychotherapy can be reported by the patients themselves, the observation of family members or a third party. However, this study adopts the viewpoint of Gordon (2000), which suggests that the subjective report of the patients is most important as it can truly reflect the treatment effect. This research mainly uses the following questionnaires to assess the satisfaction, the expectation and the evaluation of patients: the Client Satisfaction Questionnaire (Greenfield, 1989), the Psychotherapy Expectations Questionnaire (Bleyen et al., 2001), and the Session Evaluation Questionnaire (Stiles et al., 2002).

This research builds a dose-effect model to study the relationship between the frequency of sessions and the treatment effectiveness. For the individual patients, it involves the probability of symptom improvement. The subjects in this research are supposed to complete the questionnaires before each session, both during the process of psychotherapy and before the treatment.

**ANALYSES**

The data will be processed through analyzing the differences in gender, age groups, education, employment status, reasons of clinic visits and treatment history, etc. Descriptive statistics of the questionnaire results will be provided to demonstrate the individual characteristics among the various groups of subjects. The patients’ subjective feelings to treatment effect, i.e. their degree of satisfaction, expectancy, and evaluation, and their relationship with other variables will also be analyzed.

A survival analysis dealing with the survival time and event will be conducted in this research. In outpatient psychotherapy, the survival time refers to the session’s number of times, which exhibits complex distribution. As there are great differences in session frequencies among the patients. The survival event involves whether the subjects get better or worse, or even have no progress in curing. The current study mainly adopts Kaplan-Meier analysis using the approach of product-limit estimates.

**METHODOLOGY**

**Sample source:** the participants are from multiple mental health treatment centers over the last three years, who are diagnosed as having the recurrent depressive disorder, current episode severe without psychotic symptoms.

**Data Accessibility -** all of the data that offers details about the subjects’ engagement with the health care system currently reside in the Island Health Enterprise Data Warehouse (EDW), from 2014 to 2016, including the longitudinal clinical encounter data such as the details of clinic visits and the health care costs. All the data provided would be de-identified, and the transactions of encounter data will comply with nationally accepted regulations and practices for health data security.

**Study Limitations**

Due to the limitation of time and sample size, this research only considers the dataset over the last three years. A longitudinal study that involves a greater time span might make the research results more reliable, especially in finding the patterns of effective service models. Moreover, this study does not take into consideration an intervention experiment or other intervention means, which could be more convincing in validating the models. And the overall study adopts the lens from the subjects rather than other participants such as the therapists or a third party.

# Data management

1. The data to assess the treatment effectiveness of outpatient psychotherapy are from questionnaire survey. The encounter data entailing details of patients’ clinic visits and service providers are from the data warehouse recorded in the Island Health.
2. Where will the data be housed – extracted encounter data is restored inside the Island Health Secure Research Environment; questionnaire survey results are saved on a laptop not likely to be viewed favourably.

# Consent, Protection of Privacy

1. Consent – the development and validation of models using large volumes of de-identified data extracted from the EHR is without consent; conducting of questionnaires survey will be with the patients’ consent.

(Notes: The following details of data privacy of Part 7 and Part 8 are quoted from the provisions in the protocol template of Island Health)

1. Protection of privacy at the level of researcher access to warehoused data will be ensured through the use of three sets of controls –
   1. Administrative – agreements between Island Health and all members of the research team – specifying permitted/proscribed activities that can be performed with the research data;
   2. Technical – to prevent unauthorized access to research data; to prevent unauthorized export of person-level data from the data disclosure environment; to prevent unauthorized import of person-level data from external data sources into the data disclosure environment.
   3. Data de-identification – to minimize risk for re-identification in the event of unauthorized access or in the event that researchers engaged in activities proscribed by Data Disclosure and Access Agreements; to enable the body of research data used to generate the models to be deemed to be free from Protected Health Information, or other personal information, in order to enable legislation and policy-compliant data access without consent.

# Data retention

The Researchers work only with a copy of data from the Island Health Enterprise Data Warehouse (EDW). The copy itself is housed within the DDAE. The source data in the EDW are subject to BC provincial and Island Health data retention policies, which require that the information be retained indefinitely. The Personal Identifiers are not included in the copy of the data made accessible to the Researcher. They are stored in the EDW and are retained indefinitely.

# References

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