A. Cover

1. Project title

"Effectiveness of <u>GUI</u>deline for <u>D</u>issemination and <u>E</u>ducation on the treatment of depression, or the EGUIDE Project, Depression Version"

2. Project summary

A guideline for the treatment of depression was released in 2012 by the Japanese Society of Mood Disorders, and was revised in July 2016. It is unclear, however, if the content of the guideline has broadly disseminated; likewise, it still is not fully known if it is being reflected, and proving useful, in actual clinical practice. This project, therefore, aims to hold a training course on the guideline for the treatment of depression (2nd edition), investigate whether the guideline influences the treatment of depression in a particular medical institution, and verify the effects of the guideline on the appropriate dissemination and education of the treatment of depression.

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C. Project details

1. The project's background and objectives

Psychiatric treatment consists of two wheels: drug treatment and psychosocial treatment. Clinicians vary significantly in their practice of psychiatric treatment, calling for the need for spreading standardized medical treatment. For example, in the treatment of depression in Japan, concomitant use of multiple antidepressants and long-term use of antianxiety drugs and sleep medications have become a problem. With the former, in particular, measures have been taken in 2014 in the form of reduction in the amount of medical service fees. In 2012, the Japanese Society of Mood Disorders released a guideline for the treatment of depression, which was subsequently revised in 2016. However, it is not sufficiently clear if the guidelines are being reflected, and made useful, in actual clinical practice. This project therefore aims to hold a training session on the 2nd edition of the depression treatment guideline targeting young psychiatrists throughout Japan, examine if the guideline influences the treatment performed at their respective medical institutions, and verify the effectiveness of the guideline in disseminating and teaching appropriate depression treatment.

2. Project targets

- Individuals with less than ten years' experience as a psychiatrist
- Individuals with ten or more years of experience as a psychiatrist but who aim to receive training sessions, based on the guideline, and strive to enhance their psychiatric medical technology
- Individuals who are capable of offering information on drug prescriptions of patients whom they themselves had treated
- No age restrictions

- 3. Project members
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4. Project plans

4a. Implementation method

A training session on the 2nd edition of the guideline for treatment of depression will be held, mainly targeting young psychiatrists who are physicians who perform treatment at various universities and medical institutions. We will observe each medical institution's treatment behaviors over the years towards inpatients as well as outpatients, and examine the changes that may occur as a result of the training sessions.

The training session will be held for one day, and once a year at various regional areas. (Some regions will hold the session at multiple locations, in line with the number of participants, such as the Kanto region.) During the morning, lectures will be held on the content of the guideline, and, in the afternoon, participants will be divided into groups to carry out group discussions, using patient cases. Members who have formulated the guideline will mainly draw up the content and program of the training session, and conduct training sessions as lecturers. Materials that were formulated, based on the 2nd edition of the depression treatment guideline, and approved by the Guideline Formulation Committee, will be used as materials in the training session. As a basic rule, one subject (psychiatrist) will participate in a training session once. However, motivated individuals may participate more than once upon request.

To investigate the participants' willingness to learn the guideline, and their degree of understanding, we will administer a signed questionnaire using about ten questions during the session (twice, at the start and end of the training session). The questionnaire sheets will be collected on the day of the session, and data will be collected by the person responsible for the session. Information of the subjects such as this will be sent to Osaka University, which is the entity in charge of analysis, and analyzed anonymously.

Actual treatment is performed at the discretion of physicians who are the targets of this study, and is not performed in accordance with a specific protocol. The content of treatment is believed to be largely influenced not only by the physician's judgment, but also by the method of treatment that is possible at a particular medical institution, as well as the instructions by senior physicians and conferences. Therefore, no interventions to the content of treatment will be made.

Patient information to be collected pertains to data within the scope used in general medical treatment, and includes basic information such as age, sex, and diagnosis, as well as prescription data (e.g., monotherapy, prescription of psychotropic drugs not recommended by the guideline), method of treatment (e.g., cognitive behavioral therapy, modified electroconvulsive therapy), the severity of depression, and name of the physician in charge. Such patient information will be anonymized at the respective

medical institutions, sent to Osaka University, and used for analysis.

4b. Milestones

Verification of the usefulness of education and training (training sessions) on the guideline for the treatment of depression

Attainment period: December 2019

To verify the usefulness of the 2nd edition of the treatment guidelines of depression released by the Japanese Society of Mood Disorders, a training session targeting physicians were held at nine locations throughout Japan from October 2016 to March 2017. A total of 253 physicians from 33 institutions took part. Similar training sessions are planned to be held from October 2017 to March 2018 and from October 2018 to March 2019. We will administer a pre-and post-session questionnaire to the participants on the understanding of the guideline and motivation to perform treatment based on the guideline, and verify the sessions' short-term usefulness. In addition, to examine to what extent the training sessions influence the participants' prescription behaviors, we will focus on data that were already collected as pre-data concerning the following Quality Indicators (QI, or quality of medical treatment) that include the content of prescriptions issued by the participants' institutions prior to their participation in the training session, and confirm, in a timeline manner, how the data had changed over the years after the training session.

- Antidepressant monotherapy
- Prescription of antianxiety drugs, and reduction of their dosage
- Prescription of sleep medications, and reduction of their dosage
- Combined use of antipsychotic drugs
- Electroconvulsive treatment
- Cognitive behavioral therapy

4c. Evaluation method

As mentioned above, a questionnaire will be carried out for each training session. The degree of the enhancement of the participants' motivation for treatment based on the guideline, as well as their degree of understanding of the content of the guideline, between pre- and post-training sessions, will serve as the short-term evaluation method of usefulness, in terms of the dissemination of the 2nd edition of the depression treatment guideline and standardization of knowledge. We will also evaluate and compare the QI between before and after intervention by the training sessions at the participants' institutions, and verify the usefulness of the guideline training sessions in actual clinical practice. We will execute this plan throughout Japan for three years, and evaluate the usefulness by analyzing the results.

5. Existing project

This project was started in October 2016, and is currently under way. The results that have already been published are shown below.

- Koichiro Watanabe, Kazuyoshi Ogasawara, Takashi Tsuboi, Toshinori Nakamura, JunichiIga, Masahide Usami, Ryuji Furihata Kunihiro Iwamoto, Eiichi Katsumoto, Yoshikazu Takaesu, Hiromi Tagata, Nobuhiro Sugiyama, Kiyotaka, Nemoto, Naoki Hashimoto, Hiroshige Fujishiro, Hiroyuki Muraoka, Hisashi Yamada. Studying the depression guideline further in depth: From the EGUIDE training sessions. The 14th Annual Meeting of the Japanese Society of Mood Disorder, July 21-23 (22), 2017. Workshops
- Hiromi Tagata, Naohisa Tsujino, Ken Inada, Koichiro Watanabe, Ryota Hashimoto, Masafumi Mizuno. A study on the educational effects of the depression treatment guideline: A report on the depression training sessions. The 14th Annual Meeting of the Japanese Society of Mood Disorder, July 21-23 (22), 2017. Poster presentations
- Ryo Sawagashira, Naoki Hashimoto, Tomoya Yamamoto, Ken Inada, Koichiro Watanabe, Ryota Hashimoto, Ichiro Kusumi. A study on the effects of the guideline on the dissemination and education of psychiatric treatment: A report on the depression training sessions in the Hokkaido area. The 14th Annual Meeting of the Japanese Society of Mood Disorder, July 21-23 (21), 2017. Poster presentations

6. Publication and development of the project results

The database on patient information collected at institutions of training session participants pre- and post-sessions, as well as the patients' timeline data, serves as the data source used in assessing the results of the project. From the database, information on prescriptions relating to QI, in particular, is extracted, and changes in QI as well as factors that influence the QI are analyzed. Although this is a prospective survey, there are limitations in that there are no subject groups, and that the 2nd edition of the depression guideline has already been published, so the direct causal relationship between the evaluation results and the project cannot be shown. However, we hope to show even more solid usefulness by increasing the number of subjects.

The Health Labour Sciences Research Grant and the Health Labour Sciences Special Research Project implemented in 2011 showed that antidepressant monotherapy accounted for 78.2%, on a receipt-basis. The rate of antidepressant monotherapy, prior to the training session, at institutions where the project's participants worked is currently being analyzed, and is subject to change as the number of participating institutions increase. However, we anticipate an increase in the rate of antidepressant monotherapy, which is a QI, after taking part in the training sessions. Regarding other QIs also, as hypotheses, we anticipate results such as a reduction in the use of antianxiety drugs and sleep medications, and an association between psychotic symptoms and the concomitant use of antipsychotic drugs.

By conducting a training session itself in this study, it is expected that the 2nd edition of the depression treatment guideline becomes widespread and can provide better education on appropriate treatment to young psychiatrists, thereby resulting in even more appropriate treatment to be broadly performed. There also is the possibility that, by verifying the educational effects, a methodology on even more effective treatment education will be developed, leading to the development of a method of lifelong education of psychiatrists and paramedical staff involved in psychiatric treatment, as well as to the education of the patients and their families.

D. Project timelines

January 2018 – March 2018:

- Implement training sessions on the 2nd edition of the depression treatment guideline (second year; began in October 2017)
- Collect medical information at the participants' institutions from April to September 2017
- Administer a questionnaire at each training session to assess pre-and post-session motivation and degree of understanding

April 2018 – September 2018:

- Analyze the results of the questionnaire survey administered during the training sessions for FY2017, and publish the findings at an academic meeting
- Compare and analyze the QI pre-training session (April-September 2016) and post-session (April-September 2017), and announce the findings at an academic meeting
- Prepare for the training sessions that will begin in October 2018, as well as cultivate future lecturers for training sessions

October 2018-March 2019:

- Implement training sessions on the 2nd edition of the depression treatment guideline (third year)
- Collect medical information of April—September 2018 from the participants' institutions
- Administer a questionnaire at each training session to assess pre- and post-session motivation and degree of understanding

April–December 2019:

- Analyze the questionnaire results and QI over the years, publish the findings at academic meetings as well as in journals
- Examine the future tasks relating to the dissemination and education of depression treatment guideline