

The Longitudinal Investigation of Depression Outcomes (LIDO) Study

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Abstract:

LIDO is a multi-site observational study of unrecognized depression and its quality of life and economic correlates. The LIDO study is currently underway in 6 countries: Australia, Brazil, Israel, Russian Federation, Spain and the US. Participating primary care sites are in process of recruiting 150 depressed patients who have not received treatment for depression in the past 3 months. In all, approximately 900 patients are being followed over the course of one year to determine their concurrent medical conditions, quality of life, health care utilization, change in depression status and course of treatment. Strict adherence to study protocol across these six international sites promises to yield high quality data and important information regarding the cross-cultural course of depression in primary care, as well as to characterize the change in functioning, quality of life and health care utilization among depressed patients over time.

Background and Rationale

Depression is a serious health problem^{1,2,3} that often goes undiagnosed and untreated by primary care physicians. Little is known cross-culturally about the burden of depression, in terms of economic costs and quality of life^{4,5}. In US studies, depressed patients are high consumers of general medical resources in addition to their use of mental health services, but it is not well understood if this trend is seen cross-culturally, or when taking into account co-morbid conditions and functional limitations.

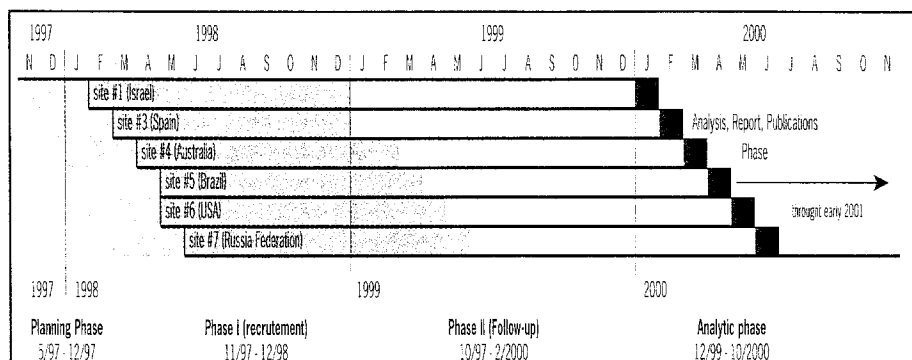
The primary objective of the LIDO study is to assess the quality of life and economic correlates of recognized clinical depression in primary care settings. This will be done in a multi-center, cross-cultural observational study design with repeated measures.

Secondary objectives of the LIDO study are

- 1) To determine change in the functioning, quality of life (QoL), and medical care utilization of people with major depression.
- 2) To describe potential predictors of change for the outcomes listed above, including severity of depression, co-morbid physical conditions, treatment status and demographic characteristics.
- 3) To describe differences in QoL and resource utilization between treated and non-treated patients with major depression.
- 4) To further refine several research tools related to QoL.
- 5) To assess the burden of depression on a primary care patient population.

Patients using primary care facilities are screened for depressive symptoms using the Center for Epidemiological Studies Depression

Figure 1: Overview of Study Phase



Site #2 was dropped

(CES-D) Scale with a cut-off point of 16. Those meeting inclusion criteria are given the Composite International Diagnostic Interview (CIDI), which has been modified for recency of symptoms, to confirm the diagnosis of current depression. If other study criteria are satisfied, those scoring positive on the CIDI (using DSM IV Criteria) are enrolled in the study for one year of follow-up in which depression status, health care utilization, functional status and quality of life are monitored. Site-specific estimates of cost of care are gathered in each country and are standardized to allow for cross-cultural comparisons. The attending primary care physician is made aware of the depression diagnosis of each patient at the beginning of the one-year follow up.

Activities

a) Study Design

The study is organized in 4 phases (Figure 1). The Planning Phase began with international meetings held in Leipzig and Seattle (1997) during which the study design and collaborative relationships were determined.

During the Recruitment Phase, international sites were enrolled on a staggered entry pattern starting with a 3-day orientation, which involved standardized training in LIDO protocol and CIDI administration. Recruitment and patient enrollment activities were begun and monitoring was done at mid and end-points of recruitment in accordance with uniform established study criteria. The Follow-up Phase involves repeated measures, data management, and continued site monitoring. To date, four sites have completed recruitment with the remaining sites ending this summer. Plans are well underway for the Analytic Phase, which begins summer 1999 after all sites complete recruitment.

b) Site Monitoring

Four separate monitoring visits per site are conducted by the Coordinating Center to ensure that all aspects of data collection, study management and interview procedures are performed in compliance with established study design and protocols. These visits also serve to insure open lines of communication and the opportunity to solve the unique problems arising at each site.

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Because validity of the diagnosis of depression is critical to the LIDO study, a site-specific CIDI Monitoring system has been established at each site to ensure the quality, consistency and uniformity in the CIDI interview data.

3. Study Organization

Health Research Associates (Seattle, WA, USA) serves as the International Coordinating Center for the LIDO study. The Research Team (consisting of representatives from five international groups) provides scientific oversight for the study, and a number of Study Advisors bring special areas of expertise to the effort. These groups, along with the six site investigators, comprise an overall Steering Committee for the study.

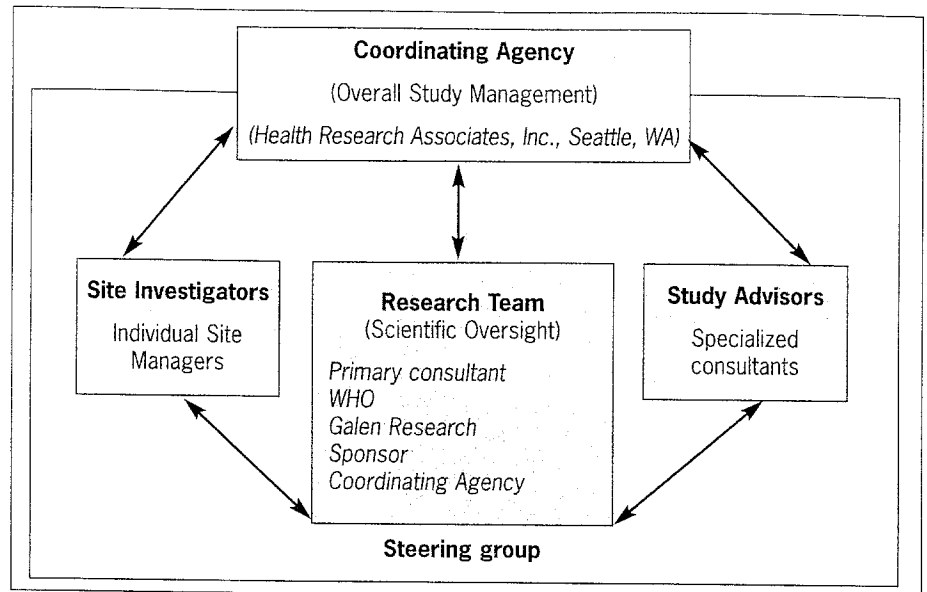
Future Directions

Analytic plans specific to depression, economic and quality of life outcomes have been developed and will guide the entire publication process. Data collection is expected to be completed by the end of summer, 2000. The first abstracts for presentation at scientific meetings are underway and manuscripts are being developed at those sites who are further into follow up. The end of recruitment will start the first round of Phase 1 manuscripts in January 2000. •

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Figure 2: Overall Study Organization



* LIDO GROUP

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