



# Knowledge Empowerment of Youth with Solid Tumors

Grant Number: R44CA86686-03

## Abbreviated Abstract

Childhood cancer is the number one disease killer of children and adolescents in North America. For adolescents, a diagnosis of cancer comes at a particularly vulnerable developmental stage in their lives. Phase I focus group interviews indicated that these adolescents are adamant about wanting to know and learn about all aspects of their disease and how it will impact their lives. Unfortunately, few educational tools exist for these young cancer patients, particularly those with solid tumors, and none are in an interactive format.

This application sought funding to complete and evaluate a multimedia CD-ROM for 12-18 year-olds with solid tumors to teach them about their disease, treatment, and coping strategies. A combination of text, videos, animations/graphics, voice-overs, music, and games was created to provide important information in an interactive and non-threatening manner. This innovative product is the first of its kind, focusing on solid tumors. It was evaluated in a randomized pre-post design against a "usual care" print handbook to determine its effect on coping skills, feelings of control over health, knowledge about solid tumors and their treatment, satisfaction, and acceptability. The CD-ROM is being marketed so that it is available to all adolescents with solid tumors, families, schools, cancer foundations and camps, libraries, and healthcare facilities.

## Primary Investigator

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Product web site: [www.conqueringcancer.net](http://www.conqueringcancer.net) (Conquering Cancer Network: Empowering Teens with Tools, Info, and Inspiring Stories - CD-ROM for adolescents with solid tumors)

Judith K. Jones, MD, PhD, President of The Degge Group, Ltd., is a clinical pharmacologist and pharmacoepidemiologist who is currently affiliated with Georgetown University, George Washington University (Washington, DC), and the University of Michigan School of Public Health Summer Program. Dr. Jones is an internationally recognized expert in the areas of adverse drug reactions and pharmacoepidemiology. She is also a long-time advocate for patient education and wrote one of the first books to empower patients: Good Housekeeping Guide to Medicines & Drugs (Hearst Corporation, 1978, 1980). Dr. Jones has had experience with various aspects of multimedia computer interface, including: 1) work with the TIME project using voice-activated videodiscs for educating medical students; 2) development and testing of a voice-activated computer system for a hypertension clinical trial to optimize data collection and reporting (as Co-Investigator on the NIH SBIR grant #

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R44 47965); and 3) collaboration in development, beta testing and initial marketing of the computerized medical record system (MEDIDOC) in the US, which was originally developed for the European market. 4) Dr. Jones served as PI on the NIH SBIR Phase II grant which produced a multimedia educational CD-ROM for children with leukemia, their families, and friends (Kidz with Leukemia: A Space Adventure, SBIR grant CA71271). She also served as PI on both Phases I and II of the NIH SBIR grants that produced and evaluated in a randomized clinical trial a multimedia educational CD-ROM for adolescents with solid tumors (Conquering Cancer Network: Empowering Teens with Tools, Info, and Inspiring Stories aka CCN, SBIR grant CA86686).

## Research Team & Affiliations

Judith K. Jones, MD, PhD (PI), President & CEO, The Degge Group, Ltd. and President, The Pharmaceutical Education & Research Institute, Inc., a non-profit organization accredited to give ACCME, ACPE continuing education credits.

Aziza T. Shad, MD, (Co-PI on project), Amey Distinguished Professor of Neuro-Oncology and Childhood Cancer Director, Division of Pediatric Hematology/Oncology, Blood and Marrow Transplantation Director, Leukemia Lymphoma Program Director, Cancer Survivorship Program Lombardi Cancer Center Georgetown University Hospital

Karen Hennessy, RN, MS, CPNP (Consulting Clinical Nurse Practitioner), The Degge Group, Ltd., and Pediatric Nurse Practitioner, Childhood Cancer Survivorship Program, Lombardi Cancer Center Georgetown University Hospital

Sharmila A. Kamani, BA (Project & Grants Manager), The Degge Group, Ltd.

Patricia J. Bush, PhD (Consultant), Professor Emeritus Georgetown University School of Medicine

## Total Budget

\$965,304.00

## Research Objectives

AIMS:

- Defining requirements for all sections of the CD-ROM;
- Conducting focus groups and evaluations to assure appropriateness of content;
- Creating storyboards and scripts for all sections of the CD-ROM;
- Developing all sections of the CD-ROM, using the latest technologies for multimedia presentation;
- Designing and developing a (CD-ROM) user's manual;
- Beta testing the CD-ROM;
- Evaluating the CD-ROM relative to use and acceptability by adolescents, families, and HCPs;
- Evaluating product's impact on adolescents' coping skills, feelings of control over health, self-efficacy, quality of life, and understanding of diagnosis and treatment of solid tumors;
- Finalizing the CD-ROM, i.e., making changes based on feedback.

## Theory/Hypothesis

An interactive multimedia CD-ROM tailored to adolescents with solid tumors has more frequent use than standard print material and more importantly, has superior effectiveness in improving cancer

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knowledge, self-efficacy, coping skills, internal locus of control, and quality of life, as well as in achieving greater acceptability as an information resource.

## Experimental Design

This was a pre-post design with randomization of adolescents with solid tumors into treatment (CD-ROM) and control (book) groups.

## Final Sample Size & Study Demographics

Sixty Sixty five (65) teens, ages 12-18, completed the study - 41 males (63.1%) males and 24 females (36.9%). The ethnic distribution was 15 (23.1%) Hispanic/Latino, and 50 (76.9%) other. The racial distribution was 52 (80.0%) White/Caucasian, 11 (16.9%) African-American, and 3.1% other. The average age was 14.8 (S.D. 1.96) years ranging from 12-18 years. As for treatment status, 50.8% of the teens were in treatment whereas 49.2% had been out of treatment an average of 14.8 months (S.D. 11.65), ranging from 6 days to 33 months. 12-18 year-olds with solid tumors of all races and ethnicities; also their parents & pediatric oncology healthcare providers.

Eligibility criteria for participating adolescents were as follows:

- Age: 12-18 years old
- Diagnosis: Solid tumor
- Treatment Status: Either on treatment or no more than 3 years since end of treatment
- Education/Literacy: No more than one grade behind in school, literate in English
- One Parent's/Guardian's education: Minimum 8th grade

## Data Collection Methods

The study was a pre-post design with subjects randomized to one of two treatment levels: the CD-ROM and a control (the "Handbook") which contains analogous information. Randomization was done centrally at The Degge Group. Each interviewer (conducting the interview in person or by telephone\*) called a Degge toll-free number to randomize a subject at the end of the pre-testing session. Each subject was assigned an ID, and after the pre-test interview, the subject received the CD-ROM or Handbook, based on their randomization. Data was collected on a structured instrument. Using only subject ID without identifying information, data was then entered into an Access database for analysis. Approximately 3 months later, the subject was interviewed again – at a post-interview session using another post-test instrument that was similarly entered into the analytic database.

\*Note: To increase the sample size, some of the interviews were conducted via phone as subjects could not come to any of the testing sites.

## Outcome Measures

The CD-ROM was evaluated relative to its effect on:

- 1) Coping strategies;
- 2) Quality of life;
- 3) Health Locus of Control;
- 4) Self-efficacy;
- 5) Cancer knowledge;

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- 6) Acceptability by families and providers;
- 7) Use by adolescents, families, and healthcare providers.

Health Locus of Control: Nine items of the 18-item Wallston Multidimensional Health Locus of Control Scale B were measured on a 6-point Likert scale from “strongly disagree” to “strongly agree.”

Quality of Life: Sixteen items loading on 2 factors of the Pediatric Oncology Quality of Life Scale (POQOLS) were selected. The POQOLS, measured on a 6-point Likert scale from “Never” to “Very frequently”, provides a total and 2 factor scores: emotional distress and physical function and role restriction. POQOLS was originally developed as a parent report measure with each statement beginning with “My child.” For this study, “I’ve” was substituted for “My child” to facilitate self-report.

Coping Style: KIDCOPE (Older Version) (Spirito et al.) measures coping in adolescents 13-18 years old and the variety of coping styles different adolescents use in particular situations. The respondents are asked first to think of a problem they had in the past two months related to their cancer. Those adolescents who insisted they had had no cancer-related problem were asked to think of another problem. The respondents were then asked to read 10 coping strategy statements and to rate each to measure frequency of use and how much it helped. Frequency of use was measured on a 4-point Likert scale from “Not at all” to “Almost all the time.” A 5-point scale, “Not at all” to “Very much,” measured how much the strategy helped.

Self-efficacy: To measure self-efficacy, subjects are most commonly asked their degree of confidence to perform a specific task. Because SE is task-related, it is usually quite specific. The decision was to use a question that had been used for another SE scale administered to students, which had shown good internal reliability and factor scores. The question was, “How sure are you that you can do each of the following almost all of the time?” That question was followed by 10 statements about behaviors that were explicitly addressed in the CD-ROM. Measurement was on a 5-point Likert scale from “Not at all” to “Very sure”.

Cancer Knowledge: The answers were required to be in both the CD-ROM and the handbook. Four choices were offered with adolescents asked to circle all they thought were correct.

Acceptability and Use: Inquired about the following: use frequency, who used it (book/CD), amount of time spent, ease of use, likes/dislikes, availability preferences. HCPs completed brief self-administered questionnaires relative to the CD-ROM to assess acceptability and availability preferences

## Evaluation Methods

At the pre-post sessions, teens were interviewed in person or via phone by trained healthcare professionals using questionnaires. Both the teen and the interviewer had a copy of the questionnaire. Teens read the questions aloud and provided answers which were marked on both sets of the questionnaire; if necessary, the interviewers provided assistance reading along. Approximately 3 months later, after receiving the handbook or the CD-ROM, the same questionnaires were completed in post-interview sessions. An additional use and acceptability survey was conducted with parents/guardians of teens in addition to the teens themselves.



## Research Results

Relative to teens receiving the handbook, those receiving the CD-ROM were significantly more likely to increase their internal Cancer Locus of Control scores from the pre- to the post-intervention measurement. However, no significant differences were observed on the following measures: Quality of Life, Self-Efficacy, Coping Styles, or Cancer Knowledge. Failure to find significant differences for these measures was attributable in part to the study's sample size.

Acceptability was higher in the CD-ROM group of teens compared to the handbook group but not different between the parent groups. Overall, pediatric oncology healthcare providers gave high marks to the CD-ROM.

## Barriers & Solutions

The primary barrier was achieving an adequate sample of these intermittently disabled eligible patients for participation. While every effort was made to recruit patients at several clinical sites, due to several characteristics of this population, it was very difficult to obtain commitment for the duration of the study. In an effort to overcome this, Degge recruited more subjects via advertisements and conducted telephone interviews.

## Product(s) Developed from This Research

Conquering Cancer Network: Empowering Teens with Tools, Info, and Inspiring Stories