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Intervention

Improving informed consent to chemotherapy: A randomized controlled trial of written information versus an interactive multimedia CD-ROM

Ian N. Olver [a,c,*], Hayley S. Whitford [a,b], Linley A. Denson [b], Melissa J. Peterson [a], Scott I. Olver [a]

[a] *Royal Adelaide Hospital Cancer Centre, Adelaide, South Australia, Australia*
[b] *School of Psychology, University of Adelaide, Adelaide, South Australia, Australia*
[c] *Cancer Council Australia, Sydney, New South Wales, Australia*

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ABSTRACT

Objective: This randomized controlled trial aimed to determine whether an interactive CD-ROM improved cancer patients' recall of chemotherapy treatment information over standard written information, and whether demographic, cognitive, and psychological factors better predicted recall than this format of delivery.
Methods: One-hundred-and-one new patients about to commence chemotherapy were randomized to receive written information or a CD-ROM containing treatment information before giving informed consent. Patients' recall, concentration, short-term memory, reading comprehension, anxiety, depression, and coping styles were assessed with standardized measures pre-treatment. Seventy-seven patients completed tests for recall of treatment information before their second chemotherapy session.
Results: Intention-to-treat analyses indicated no significant differences between the written information and CD-ROM groups across recall questions about number of drugs received ($p = .43$), treatment length ($p = .23$), and treatment goal ($p = .69$). Binary logistic regressions indicated that for groups combined different variables predicted each of the recall questions.
Conclusion: An interactive CD-ROM did not improve cancer patients' recall of treatment information enough to warrant changes in consent procedures.
Practice implications: Different variables predicted recall of different treatment aspects highlighting the complex nature of attempting to improve patient recall. Attending to the effect of depression on patient knowledge and understanding appears paramount.

1. Introduction

The advancing sophistication of medical treatment necessitates a more refined understanding of the process of informed consent. Much has been done to attempt to improve universally poor patient recall and understanding of treatment information including improving or enhancing the ways in which information is communicated. Many studies have compared alternative formats of information given to patients for educational, decision-making, or informed consent reasons. Standard care (usually written information) has been compared with or replaced by other formats such as enhanced print formats [1], information booklets [2], structured interviews [3], audio and video recordings [4–6], and interactive computer-based formats [7–11].

Multimedia formats of informed consent are gaining much attention given society's reliance on computers and the Internet. CD-ROMs and online information can include interactive text, audio, graphics, and video, and patients have the ability to access information in the order they prefer. Computer access is more common and less expensive than in previous years and much research has found that regardless of age, accessing treatment or procedural information in multimedia formats can increase patients' knowledge and satisfaction, and is generally comfortable for patients even despite no previous experience with computers or CD-ROMs [10,12,13].

Lewis [14] presented a review of the literature and meta-analysis of computer-based technology in patient healthcare education based on peer-reviewed articles indexed in MEDLINE or CINAHL between 1971 and 1998. Out of 66 articles identified, most (45) were descriptive or anecdotal in nature. However, of the

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[*] Corresponding author at: Cancer Council Australia, PO Box 4708, Sydney, New South Wales 2001, Australia. Tel.: +61 2 8063 4100; fax: +61 2 8063 4101.
E-mail address: ian.olver@cancer.org.au (I.N. Olver).

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21 research-based articles, 13 described improvements in patient knowledge or clinical outcomes when computer-based education was compared with standard instructions thus supporting multimedia tools as effective in the transmission of knowledge or skill building.

Since Lewis [14] conducted the above review more randomized controlled trials have been published. Specifically, Enzenhofer et al. [7] conducted a randomized controlled trial testing differences in the satisfaction, knowledge, and time taken by 56 patients to view procedure information using standard physician information and an information leaflet or a computer-based visualisation tool alongside physician information. The patients were due to undergo coronary catheters or endoscopy procedures. Results indicated that patient satisfaction and patient knowledge of procedure elements were significantly higher in the computer-based group even after controlling for demographics.

Similarly, Rostom et al. [10] compared standardized audio-booklet and individualized computerized consent procedures for hormone replacement therapy (HRT) in a randomized controlled trial of 51 peri-menopausal women. The computerized version had the same information and visual format as the standardized audio-booklet form but also included a self-test and feedback module to reinforce and correct the patient. Results indicated that the computerized group retained significantly more knowledge and gained more realistic expectations about treatment than the audio-booklet group even after controlling for pre-consent knowledge and demographic variables. However, results still indicated that despite generally high educational levels, many patients were still unaware of essential information contained in the consent procedures showing that other factors impact on patients' recall and understanding.

Beyond format modifications to consent procedures, research has also examined the impact that individual differences have on a patient's ability to recall treatment information. In a structured review of the literature, Sugarman et al. [15] concluded that, based on 99 diverse articles on informed consent, diminished understanding of consent procedures was associated with older age and fewer years of education. For instance, Lavelle-Jones et al. [16] found in a study of 265 surgery patients presented with either oral or written treatment information prior to consent, that the younger patients with higher IQs recalled more important information following surgery.

Much research in the informed consent area has examined the impact of patient anxiety. However, most have assessed the impact that format modifications have had on resulting patient anxiety during or after treatment [13,17–19]. In a review of patients' memory for medical information, Kessels [20] suggested that anxiety impacts on recall as the stressful or emotional central message is the primary focus of the patient and all other information is peripheral and not processed or stored (attentional narrowing). The amount of information recalled is related to its subjective importance therefore diagnosis is usually perceived as more important than treatment information, evidence of the 'primary effect' hypothesis. Kessels [20] also suggested that the greater the amount of information presented, the lower the proportion correctly recalled. Defects in encoding and storage rather than retrieval are the key factors in why older patients forget information conveyed about treatment.

Essentially, the research on how individual differences affect patient recall of treatment information is generally sparse and under represented. This study therefore attempted to examine a diverse range of individual differences alongside format modifications to consent information. Specifically, it was hypothesized that multimedia consent information to chemotherapy in the form of a CD-ROM would be better recalled than information presented in the standard format (written information). Secondly, demographic, cognitive, and psychological characteristics of cancer patients at the time of consent were examined to determine whether they better predicted recall of chemotherapy treatment information than the format of delivery (written versus multimedia information). Finally, as many studies comparing format modifications lost much data to follow-up, intention-to-treat analyses were used as conservative estimates of outcomes.

2. Methods

2.1. Patients

Consecutive chemotherapy naïve cancer patients who were not involved in clinical trials were approached during inpatient and outpatient attendance at the Royal Adelaide Hospital (RAH) Medical Oncology Unit by consulting clinicians. Inclusion criteria required patients be aged 18 years or above, have a life expectancy of at least 12 weeks, be English speaking, and have the ability to provide consent. Patients were excluded from participation if they had a co-morbidity involving a significant psychiatric or cognitive disability, or if cognitive functioning was affected, such as with cerebral metastases. Following approval of the study by the institutional ethics committee, patients who provided their clinician with written consent to enter the trial were randomly allocated by data managers to one of two arms of the study (intervention or control) using odd/even hospital identification numbers. Clinicians therefore remained blinded to group allocation.

One-hundred-and-one patients were accrued between June 2002 and July 2006; 47 (46.5%) to the CD-ROM group and 54 (53.5%) to the written information group. Out of the 101, a total of 77 patients provided completed follow-up Time 2 data (76.2% response rate), 13 did not complete initial Time 1 testing due to illness immediately preceding or during the assessment, 10 patients did not provide any follow-up data, and one patient provided follow-up data, but no recall data, because they were too ill or they refused further participation (see Fig. 1).

2.2. Data collection

Data collection was completed in two phases. Psychological assessment of patients' cognitive abilities (immediate and delayed recall and thematic recall, short-term memory, concentration, IQ) and emotional status (anxiety, depression, coping styles) were assessed at the time of chemotherapy treatment consent (Time 1: pre-information). Thematic recall is an indication that the individual has an understanding of the main themes of a story whereas general recall refers to correct responses for each story unit recalled verbatim. Patient recall of treatment information and demographic details were collected preceding their second chemotherapy treatment (Time 2: post-information).

Time 1: Patients were seen individually by a psychologist who administered a battery of tests assessing cognitive abilities and emotional status. On average, the battery of tests took 60 min to administer. Specific assessments included the National Adult Reading Test (NART) [21]; Wechsler Memory Scale—third edition (WMS-III) [22] subtests including Logical Memory I & II, Letter Number Sequencing & Digit Span; Wechsler Individual Achievement Test—second edition (WIAT-II) [23] Reading Comprehension; Hospital Anxiety and Depression Scale (HADS) [24]; and the Mental Adjustment to Cancer (MAC) scale [25].

Following cognitive and psychological assessment, nurses provided patients allocated to the control group (written information) with the hospital's standard information sheet and