

<p align="center">APPROVED by IRD Institutional Review Board 01 Mar 2018 28 Feb 2019 Approved on Expires on DO NOT USE THIS CONSENT AFTER APPROVAL EXPIRY</p>	<p>IRB Number : IRD_IRB_2017_10_004 PI : Nomi Waqas Gul PI version Date : 22 Jan 2018</p>
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CONSENT FORM

Study Title: Effect of nurse-led education on parent's anxiety and depression on managing side effects of chemotherapy

What you should know about this study

- You are being asked to join a research study.
- This consent form explains the research study and your part in the study.
- You are a volunteer. You have the right to choose whether to participate or not participate in this study. If you decide to participate and later change your mind, you may do so without any penalty or consequences to your treatment here.

RESEARCH PURPOSE:

To measure the effect of nurse-led multimedia education, booklet providence and telephonic follow up about chemotherapy and side effects management on parent's anxiety and depression of children receiving chemotherapy first time.

WHAT YOU WILL BE ASKED TO DO IN THIS STUDY

Interview:

The questions we will ask you are about your Personal information focusing Child Name, Child Age, Child gender, Primary Caretaker, Residency and Phone number, (2) Section (B), Socioeconomic and educational status of Child caretaker focusing Occupation, Level of education, Employment status, Income per month and Treatment Expenses. (3) Section C, Cancer Information focusing Diagnoses, Type of cancer, Stage of cancer, treatment being sought, Duration of Chemotherapy, Date of diagnoses, Duration of diagnoses, Family History of cancer and Number of cancer patients in the family of the patient other than himself. (4) Section (D), Pain scale focusing Pain felt by the child now and (5) Section (E), General information related to Anxiety and depression focusing, Caregivers awareness of whether he or she was anxious and depressed? Did caregivers taken any treatment sought for his anxiety and depression. Whether any health professional advises the Caregivers, and Do caregiver, have smoking habits.

Questionnaire:

There are 21 questions in this scale equally divided in to three parts having seven questions for Depression, Anxiety and stress respectively. Each question has four level of measurement 0, 1, 2 and 3, represent past week experiences. 0 means not applicable to person, 1 means applicable to some degree or sometime, 2 means applicable to considerable degree or good part of time, 3 means applicable to person very much or most of the time. Each question is separate for Stress(s), Anxiety (a) and Depression (d). The questions focusing the concept (1) (s) hard to wind down, (2)(a) dryness of mouth, (3)(d) experience of positive feeling, (4)(a) breathing difficulty, (5)(d) difficulty in initiation of work, (6)(s) overreaction according to situation, (7)(a) experience of trembling in hand, (8)(s) use of excessive nervous energy, (9)(a) worriedness about panic situation, (10)(d) noting to look forward, (11)(s) getting agitated, (12)(s) difficulty in relaxation, (13)(d) feeling of downhearted and blue, (14)(s) lack of tolerance, (15)(a) feeling of panic, (16)(d) lack of enthusiasm, (17)(d) lack of worthiness as a person, (18)(s) feeling of somewhat

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sensitive, (19)(a) palpitation and increase of heart beat, (20)(a) feeling of scary and (21)(d) feeling of meaningless life.

Time for interview:

The questionnaire will only take about 10-15 minutes of your time.

PRIVACY: We assure you that all your information and responses will be kept secret. We will use ID numbers instead of your name. Your name will not be given to anyone without your consent. Your doctor, TB researchers from Indus Hospital will be able to look at your medical records. It is possible that research papers may be published for scientific purposes; however, your name nor that of any other participant will not be used.

RISKS AND DISCOMFORT: Some of the questions we will ask you are very personal. You may choose not to answer any questions that you do not want to. If you choose to answer, we assure you that all your responses will be kept confidential.

BENEFITS:

Before chemotherapy:

1. Multimedia education: The Intervention group will have received 60 minutes of power point multimedia education in Urdu about chemotherapy, side effect and nutritional guide.
2. Booklet provision: A booklet "Chemotherapy and you" in Urdu translation will be provided to the parents focusing detailed information about chemotherapy and side effects management.

After chemotherapy:

Follow up will be done, during follow up side effect appear in their child will be determined and the parents will be re-educated per their appearance. There are 18 side effect of chemo in booklet and it is not necessary that all will appear, e.g. example after chemo the child may developed vomiting and diarrhea but other 16 side effect may remain silent and may appear later.

3. Tele-Nursing follow-up:

- 3.1 (a) The parents will be provided opportunity to call from 9:00 a.m. to 5:00 p.m., in any week day to ask question related chemotherapy and side effect management according to booklet. The education will be again provided according to the booklet. If any information asked by parents will not be related to the booklet, will be referred to their primary consultant.
- 3.2 (b) each parent will be called by the researcher on weekly bases according to following schedule, date of education (day 0) to 7, 14, 21 and 28 day. The content will focus (i) list of problem related to chemotherapy side effect and (ii) Management techniques according to booklet. The approximate duration of call will be 15 minutes depend upon the problems identified by the parents.

ALTERNATIVE: If the interview determines that you may benefit from this research, it is your choice whether you want to avail it or not.

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WITHDRAWAL WITHOUT PREJUDICE: If you decide not to participate in this research, your treatment at the hospital will continue as usual. Even after signing this consent form, you may stop participating at any time during the interview.

COST OF TAKING PART IN RESEARCH: You do not have to pay for taking part in this study.

PAYMENT FOR TAKING PART IN RESEARCH: You will not get money to be part of this study.

QUESTIONS

If you have questions about this research, you may contact Nomi Waqas Gul Student Master of Science in Nursing contact 03452506790

If you have questions about your rights in a research study as a volunteer, call or contact the Interactive Research & Development-IRB office between office hours on Monday to Friday 9am – 5pm at the Indus Hospital (Mobile 03008272693)

SIGNATURES

If you agree to participate in this study, please sign this form. You will receive a copy of this form.

Sign of study volunteer/participant: _____

Date:_____

Sign of person taking consent: _____

Date: _____