1 Research Methodology

1.1 Study Title

The effects of chemotherapy on patients' nutritional status and distress levels.

1.2 Research Objectives

- To determine whether there is a positive or negative correlation, or no correlation at all, between actual nutritional status (as represented by body mass index) and reported distress level in patients receiving chemotherapy.
- To compare nutritional status of the patients as perceived by themselves with their actual nutritional status at data collection points 1 and 3. It is possible that patient perceptions of their nutritional status may be inaccurate but remain influential in their subsequent experience of chemotherapy and side effects (reporting of distress).
- To profile patients' perceived nutritional status of the patients at different stages of their treatment cycle. This is interesting because we might anticipate a gradual deterioration in perception of nutritional status as chemotherapy side effects develop.
- To determine, at data gathering point 3 and after collection of other data set material, whether the patients perceived that in some way their nutritional status insulated them from distress associated with chemotherapy side effects.

1.3 Sample

The sample was chosen from patients being treated for the first time for leukaemias, lymphomas and myelomas, in the haematology unit of the main acute general hospital in Malta over the months of March to May 2009 (number =13). The patients were under the care of the same Medical Consultant. During the year 2008, since the unit has been opened, the total number of patients who entered this unit for initial treatment for the above-mentioned conditions was 25. The current study sample therefore approximates to 65% of the

number of patients commencing treatment for these illnesses over the course of the previous year. The study sample consisted of a convenience sample composed of all patients who were admitted to this particular unit within the period of data collection for the initial course of treatment and during four months of enquiry as indicated above. The allocation of patients to the study population was determined by their date of admission to a particular unit for treatment of a haematological cancer by chemotherapy. These added up to a total of 15. Of these one refused to participate and another was not in a condition to answer the questions reliably. Due to these factors, it could be argued that the results can be generalised to other patients with the same haematological cancers within this location (Treece & Treece, 1986). Caveats have to be acknowledged though, these associated with extraneous factors affecting distress – the availability of family support for example.

The sample has face validity because data is gathered from individuals undergoing the treatment programme in question and within the unit where research was conducted. However, as the study deals with a sample of patients acquired over a few months, and those finally agreeing to participate might not be representative of the larger population of patients treated for all cancers in this hospital, observations about what the data tells us will need to be tentative. Nevertheless, thirteen patients represent a significant percentage of all such patients treated in the Malta unit to date (65%). Whilst we must be cautious about what a correlation study can do (drawing others attention to what has been found to coincide and not to claim causation), there does seem sufficient patients in this sample to offer some illuminative data and to speculate carefully about what has been noted so far.

1.4 Research Design

In this research study, both quantitative and qualitative data is collected. The primary purpose of using both qualitative and quantitative data collection methods was to conduct a more complete research project. Qualitative research aims to understand the nature of human phenomena and the meanings they have for the individuals involved. It was used in this study to explore patient perceptions of the relationship between nutritional status and distress at study end. Quantitative data was used to measure the more quantifiable data such as nutritional status scores (B.M.I.) and distress levels, for the sake of comparison and correlation.

Data is used and valued differently dependent on which paradigm drives the enquiry. The positivist paradigm originated from the physical sciences and empirical evidence was the only acceptable source of knowledge, internal subjective experience was negated as a source of scientifically approved knowledge" (Sela-Smith, 2002, p. 59). Positivist researchers claim neutrality and objectivity. The objective stance of the positivist researcher involves remaining "distant from and independent from those being researched" (Cresswell, 1994, p. 2). Naturalistic research gathering qualitative data, were created to report different views of human beings. "Qualitative methods are generally regarded as being less 'scientific', less concerned with causality, descriptive rather than explanatory, exploratory rather than testing" (Cauchman & Dawson, 1990, p. 112).

As quantitative research methods and positivist assumptions about the world originated from the physical sciences, naturalistic research gathering qualitative data emerged from within humanistic disciplines like anthropology, sociology and psychology. Underlying the

naturalistic approach is the assumption that "human beings not only react but act upon and create the meaning of their experiences so that inner and external realities interact and cannot be separated" (Cormack, 1990, p. 120). Whilst, in this study, nutritional status might be represented in strictly numerical terms (as a B.M.I. score), levels of distress associated with chemotherapy were incompletely expressed in numerical rating scales. Therefore, as I was studying correlates one of which is empirical and open to measurement (nutritional status) and the other of which is psychological/perceptual (distress), it was necessary to deal in both quantitative and qualitative data. Distress could and has been rated in scales, but I was also interested at last in patient perceptions. While doing so, I sought a design that would allow for, as far as possible, objective comparison of data and the search for an association between nutritional status and the effects of chemotherapy. In doing so I also tried to limit biases associated with the merits of nutritional therapy. For this reason I made all the tools suitable to be filled in by the patients themselves and I introduced a patient advisor who would check the clarity and accessibility of questions asked, tools used. I therefore asked the patients to fill in all the tools themselves and only used other data that was readily available on the unit, such as the weight and height of the patients, according to the permissions I had been granted by the local research ethics committee. I gathered the data in as dispassionate and as objective a way as possible, ensuring that the same sorts of data were gathered from each patient at similar points in treatment.

Polinghorne (1983) writes that "Human science seeks to know the reality of our experience, actions and expression." (p. 280). McLoed (1994) suggests that a researcher who wants to understand "what things mean to people" (p. 177) and who tries to achieve this, needs to choose a qualitative approach. That is why I included qualitative tools together with the quantitative ones. I aim to adopt a more ethical approach and maintain my objectivity, by

asking the patients to respond to the research tools as freely as possible. The quantitative tools were also important however, as they produced empirical, numerical data that could be statistically analysed and possible correlations identified. From the data collected I could compare the patients' actual nutritional status (via a Body Mass Index (B.M.I.) score) with their perceived nutritional status. The scope of this was to study the perception of the patients regarding to their nutritional status. The tools, apart from the initial B.M.I., were all patient-scored, thus including patient assessment, belief and judgement into the equation.

1.5 Some Possible Correlations

I would like to emphasise that where correlations are found, this study can at best, and very cautiously, speculate about the nature of the relationship. It is for other, future studies to explore causative relationships, answering questions posed here.

A number of correlations seemed possible, such as:

- Overweight or obese status (as measured by B.M.I. readings that lie between 25 and 30 kg/m^2) might correlate with low levels of chemotherapy side effect reported distress (a distress score of 3 or below)). We might carefully speculate about the insulating effects of nutritional reserve upon distress. This would only operate though if the patient also perceived themselves to be overweight/obese ('able to lose a few pounds without damage'). More details on B.M.I. are outlined in Section 3.10.1 (see dissertation page 37).

- Underweight status, as measured by B.M.I. reading that lies below 20 kg/m^2, might correlate with high levels of chemotherapy side effect reported distress (as expressed in terms of a distress score of 8 or greater)

- Patients receiving nutritional supplements correlate with those reporting successful maintenance of B.M.I. commensurate with that reported at the start of the treatment regimen.

- Patients receiving nutritional supplements correlate with those reporting low levels of distress (as represented by a score of 3 or less).

1.6 Correlational Research

The research approach that I chose to employ for his research study is the correlation approach. Correlation studies are designed to identify possible associations between two important sets of data (nutritional and distress). Because in this study different groups of correlates were gathered (B.M.I. at different points in the study and similarly reported distress at different points, actual and perceived nutritional status, as well as the use of nutritional supplements – a number of different correlations were open to exploration. In correlation studies the goal is not to prove a causative relationship (X causes Y) but to examine associations. In the nutritional care of patients this is important because assessment of nutritional status, or perceived nutritional status, may have a different part to play in assisting patients to deal with chemotherapy. For example, if an overweight/obese nutritional status was associated with a low level of chemotherapy distress (what we might think of as a physiological or psychological nutritional reserve theory) then we might target those patients with poor nutritional status for additional psychological support measures. It is not the case that we have proven that excess nutritional reserve reduces distress within patients receiving

chemotherapy, but rather that we simply note an association and might therefore concentrate our support on patients where the converse association is noted (high distress).

In this correlation study I gather data about the three sets of variables:

- B.M.I. was used to gather data about the patients' actual nutritional status,
- Patient-reported perceptions were gathered to assess perceived nutritional status, and
- The modified Distress Thermometer Score was used to quantify the patients' perceived chemotherapy-induced distress level.

Subsequently I also gathered data (after all other data gathering was complete), regarding any associations that patients themselves made between nutritional status and levels of chemotherapy related distress. This was purposefully left until last so as not to lead the respondents to report experiences associated with distress that confirmed or disproved a theory of my own making.

Correlation is a statistical technique that can show whether and how strongly pairs of variables are related (Siegle, 2009; The Survey System, 2009). Correlation studies can also be used when there is no attempt to manipulate any of the variables (Siegle, 2009), as in the case of this study. For example, readings of B.M.I. are routinely recorded with these patients as part of the clinical regimen. Siegle (2009) stresses that "Correlations only describe the relationship (between variables), they do not prove cause and effect. Correlation is a necessary, but not a sufficient condition for determining causality". There are various methods of determining correlation, the most common being the Pearson (or product-

moment) correlation (The Survey System, 2009). In the Pearson correlation data is analysed so as to establish whether there is a correlation between the two chosen correlates, one that is described as significant at the 0.05 level. Results are unambiguous where there is a consistency between the two correlates (where one results, the other also occurs, e.g. – and speculatively – obesity and low levels of distress) or where there is absolutely no relationship apart between the two (e.g. obesity simply does not coincide with any other variable in a consistent fashion). An ambiguous finding is one where there is sometimes a relationship at a level that does not reach significance and therefore where we are unable to speculate further. According to The Survey System (2009), correlation works where data is quantifiable, i.e. where numbers are meaningful. Where rating scales are involved, The Survey System (2009) states that, "correlations are not like quantities" as they state that one cannot be sure what the different respondents understand by a rating scale of 2 (for example in terms of distress level). Nevertheless, they continue, "many researchers do use correlations with rating scales, becuase the results usually reflect the real world" (The Survey System, 2009). In such cases, correlations can provide general indications.

To help target a search for possible correlations, it is sometimes helpful to profile the sets of data, for each patient. Not only is change more apparent (for instance in terms of distress) but I might note interesting apparent correlations between variables that seem to crop up in more than one patient. After the different data sets have been gathered (and in this study profiled by patient as well) statistical analysis is undertaken to search for possible correlations between the different data sets those pertaining to B.M.I., to nutritional supplement status and to levels of distress). I then describe those correlations and discuss the possible significance of the same (this in association with a qualified statistician).

1.7 Ethical Considerations

As with all research studies, especially those that involve hospital patients, ethical concerns must be considered.

1.7.1 Obtaining Access and Use of Instrument Rights

I obtained permissions from the Director of Nursing Services, the Departmental Nursing Managers in charge of the ward and of the specialist nurses, the Medical Superintendent, the Consultant taking care of the patients, the Ward Nursing Officer directly in charge of the unit, the Haematology Nurse Specialist, the nurses taking care of the patients, and the patients and/or their relatives. I also chose a patient who had received chemotherapy just like that of the patients studied and involved him as a patient advisor to the study. His role was to examine the research methodology and the tools used, to determine whether they would seem comprehensible and accessible to patients. Research methodology of the study was then adapted according to the recommendations of this Patient-Advisor. Letters of consent are provided in the appendices (see Appendices – page **Error! Bookmark not defined.**). The proposal for the study was also passed by the Ethical Committee of the University of Malta. Appendix **Error! Reference source not found.** (on dissertation page **Error! Bookmark not defined.**) also contains a permission letter that I have officially obtained to use the Distress Thermometer Problem Score (see later description and tool at Appendix **Error! Reference source not found.** (on dissertation page **Error! Bookmark not defined.**)) for the duration of this research project from its author (NCCN, 2008).

1.7.2 Dealing with Ethical Issues

Before starting the assessments, I agreed that the Haematology Nurse Specialist would inform all the patients about the research project and what I intended to investigate. She had been following these patients throughout their diagnostic tests and preparing them for their treatment and hence had already built a trusting relationship with the patients. As the study was conceived of as working in two stages (stage one gathering correlates, stage two inviting patient opinion on possible relationships between nutrition and distress) and explaining the second of these stages could prejudice responses to the first, it was agreed that the Haematology Nurse Specialist would explain our interest in experience of chemotherapy and in nutritional status, but only brief the participants on the second stage interest in perceived relationships between the two later, when we at last asked them whether they thought nutrition was linked to chemotherapy distress in some way. In stage 1 it was important to gather nutritional and distress data without drawing the participants' attention to possible links. The method of assessment was explained to the patients, as well as how the research study would be carried out and for how many times they would be asked to provide data (see Table 1 - Data collection summary, on dissertation page 14). The aim of the study was also explained to them and they were also informed that the consultant, doctors and nurses in charge of their care had been informed beforehand.

1.7.3 Information to the participants

Participants were provided with an information sheet (in English and Maltese) explaining the study (see Appendix **Error! Reference source not found.** (dissertation page **Error! Bookmark not defined.**) and Appendix **Error! Reference source not found.** (dissertation page **Error! Bookmark not defined.**)). Importantly, patients were not alerted to the working premises associated with this study (i.e. that there might have been correlations

between positive nutritional status [actual or perceived] and lower levels of chemotherapy related distress). However, sufficient information was shared with patients to help them to determine the nature of contribution they were asked to make, the effort required and the possible consequences that could attend talking about their treatment. Therefore, whilst patients were not deliberately deceived about the purpose of the study, it was arranged that different facets of data would be gathered at different stages and so as not to distort responses (prompting the patient to respond in ways that they hoped would please me). In this sense, it was thought that the patient would develop a growing insight into the study, already ethical at start, but increasingly insightful by study end. This arrangement was necessary if potential correlations between nutrition and intensity of the side-effects were to be studied in a rigorous way. Only at data gathering point 3 were they invited to express views on any links that they perceived between nutrition and distress. In this way, I avoided the patients giving answers that they believed I might have wanted to hear, such as that nutrition decreases the intensity of the side-effects and could search for possible correlations and later to identify any perceived correlations that the patient thought were important.

Participants were also asked to sign a written consent once all the details had been explained to them (see Appendix**Error! Reference source not found.** (dissertation page **Error! Bookmark not defined.**)). They were also assured that all information would remain confidential and that no names would be collected/reported within the study. For this reason, each participant was given a reference number and only a contact telephone number was taken, just in case I needed to contact the participants when they were at home. These details and the filled-in tools were handled only by me. The contact telephone numbers and the corresponding patient reference numbers were kept on a separate sheet and were burnt once all the study results were collected. The participants were also given a Complaint Form (see

Appendix **Error! Reference source not found.** (dissertation page **Error! Bookmark not defined.**)) where the participants could file a complaint that the Nurse-in-Charge of the unit herself would then present to the Ethics Committee of the University of Malta or the Research Supervisor. This would give the participant the option to clarify any queries or arrange or stop any anomalies that s/he felt were taking place within the study. At that point, the participants could either proceed with their participation in the study or retire.

1.8 Interventions on and rights of the participants

There were no physical interventions or treatments associated with this study, save for the measurement of B.M.I. and distress levels. Actual B.M.I. recordings were routinely made within the ward, whilst perceived B.M.I. records were added. The study invited the patient to respond to a number of questions. There was however, the theoretical risk that in gathering such data the study would further sensitize the patient to their circumstances. For that reason, I arranged that any participant who wished to, could be referred to a suitably qualified nurse-psychologist or counsellor, to talk about their emergent feelings associated with their diagnosis, treatment or research participation. All patients in this study had routinely shared a discussion with a clinical psychologist in any case, this associated with anxieties that might attend their diagnosis and treatment.

Patients were also given the opportunity to receive a short summary of the research at the study end – this as part of their consent form. In this way they would obtain a useful overview of study findings but without disclosure of other patient identity. The same summary of research findings was submitted to the research ethics committee at study end

and is included in Appendix **Error! Reference source not found.** (on dissertation page **Error! Bookmark not defined.**).

1.9 Involvement of the Patient Advisor

I had initially intended to collect data at four points during the treatment cycle, one before the treatment, one at day 7, one at day 14 and one after the cycle (day 28). However, as several cycles exist where some patients take 28 days while others take less and others take even longer, this layout could not be carried out. The Patient Advisor stated that he felt that there would be absolutely no change in the scores of all the assessment scores between the second and the third assessment, i.e. between the two assessments taken during the treatment. The main differences, he felt, would rather emerge between the beginning and the end of the treatment cycle, i.e. before and after the side-effects of the chemotherapy would have started manifesting themselves. I therefore decided to eliminate one assessment and to conduct one assessment before the treatment, one during the treatment and one after the treatment. An outline of the data gathering process can be seen on Table 1 (on dissertation page 14). This also had the added advantage of leaving the patients more at peace, rather than subjecting them to another assessment which, after all, was not proving to be useful. From the discussion with the patient advisor, the tools proved to be acceptable to patients and provide all the data that I was intending to. As the original tool had been already validated in other studies I decided to keep the tool and rather than augment it. The Patient Advisor also examined the tools to see whether they were user-friendly and compatible for use with the treatment cycle and understandable for the patients. The Patient Advisor himself filled in the tools and helped me adapt the tools for them to be coherent with the treatment cycle as well as to help me collect the data which would lead to achieving the scope of the study.

Data Collection Point	Patient Data Collected
1 – On patient admission and prior to the start of chemotherapy	B.M.I. (actual nutritional status) Distress Thermometer Problem Score (patient-rated distress scores) Patient-perceived nutritional status
2 – After 4 to 6 days of the start of chemotherapy (when chemotherapy side effects were adjudged to have presented given regimes used)	B.M.I. (actual nutritional status) Distress Thermometer Problem Score (patient-rated distress scores)
3 – After the end of treatment (at around 28 days from the start of treatment)	B.M.I. (actual nutritional status) Distress Thermometer Problem Score (patient-rated distress scores) Patient-perceived nutritional status & patients' perception of a possible relationship between nutritional status and side-effects of chemotherapy

Table 1 - Data collection summary

The tools used in this dissertation will now be discussed in more detail.

1.10 The Tools

I used several tools to collect the data, namely:

(1) a nutritional assessment tool – Body Mass Index, which involves a calculation of weight of the patient (in kilograms) divided by the square of their height (in metres) – data already collected by the Nursing staff on the patients' admission to the unit and hence already available on the patients' notes. More details about B.M.I. can be found in Section 1.10.1 (**Error! Reference source not found.**, page 37).

(2) one tool for patients to assess their own psychological distress, which is a result of the chemotherapy that they receive. This is an adapted version of the Distress Thermometer Problem Score (NCCN, 2008) (see Appendix **Error! Reference source not found.** (dissertation page **Error! Bookmark not defined.**)). This enables the patient to quantify their reported distress – an important process when correlation was considered.

(3) one set of questions to assess the patients' perception of their nutritional status. This is administered at data gathering point 1 (see Appendix 7.12**Error! Reference source not found.** (dissertation page156)).

(4) one set of questions to assess the patients' perception of their nutritional status and their views regarding a possible link between nutritional status and distress levels caused by the side-effects of their chemotherapy. This is administered at data gathering point 3 (see Appendix **Error! Reference source not found.** (dissertation page **Error! Bookmark not defined.**)).

All the tools chosen were filled in by the clients themselves. Hence the majority of the tools gave patient-provided data. Thus this made the data collected more objective and patient-centred, thus reducing researcher bias. The fact that the tools were validated beforehand also gave the study construct validity (Trochim, 2006). The tools used can also said to show test-retest reliability (Trochim, 2006; Cormack, 1991).

1.10.1 The Body Mass Index (B.M.I.)

Body mass index is defined as the individual's body weight divided by the square of their height. The formulas universally used in medicine produce a unit of measure of kg/m^2

(Wikipedia, 2007), as outlined in Table 2. B.M.I. indicates whether a patient is underweight, normal weight, overweight or obese and indicates something of the nutritional reserve held by a patient who faces threat by cancer and/or chemotherapy. This ratio is widely used to assess a person's weight for nutritional status.

Nutritional Status	B.M.I. Ratio (kg/m^2)
Starvation	Less than 15
Underweight	15 to 18.5
Normal	18.5 to 25
Overweight	25 to 30
Obese	30 to 40
Morbidly obese	Greater than 40

Table 2 - Nutritional Status by Body Mass Index Ratio (Wikipedia, 2007)

1.10.2 Adaptation of the Distress Thermometer

Based on evidence that psychological distress often goes unrecognised, although it is common among cancer patients, routine screening for distress (as defined in the Section entitled **Error! Reference source not found.**) is recommended (Jacobsen *et al.*, 2005). The Distress Thermometer has been validated by several studies (Ransom *et al.*, 2006; NCI, 2005; Patrick-Miller *et al.*, 2004). I was given official consent from the NCCN to use this tool during this study, both for academic year 2007-8 and again for 2008-9 (See Appendix **Error! Reference source not found.**(dissertation page **Error! Bookmark not defined.**)).

1.11 Data Collection

I collected the data via the various tools mentioned above. The patients' contact number was another way in which they could be identified as this was different for each client. Initials were taken instead of a signature, so that, in case anyone saw the results of the data collection, no one would have been able to associate them with any client. Finally I collected information about the individual patients' chemotherapy regimes for the purpose of ascertaining whether this might help to explain differences in the incidence of side effects and possible impact on levels of distress. No other personal details were asked for by me, as these were not considered to be necessary for the outcome of the study to be achieved.

1.12 Data Analysis

All patient data was entered into an Excel® spreadsheet that was prepared before the data collection, based on the data that was collected from the tools and all the other data that I thought was necessary for the purposes of the study. I tested the spreadsheet on the patient advisor, after which I made the necessary amendments to bring the spreadsheet as faithful to the tools as possible. This was entered into the spreadsheet and thus facilitated the collection and presentation of the results and the final analysis of the data.

At the start of data analysis, a profile of each patient was created, where the trends s/he showed in B.M.I., distress levels, perceived nutritional status and other variables were investigated and compared. A table was also created summarising all the data collected by patient, so that these trends could be more visible and easier to identify and analyse. The help of a qualified statistician (from the University of Malta) was also obtained who also input the data into the SPSS® (statistical analysis software) and helped the interpretation of

the data and extract conclusions and any correlation between actual nutritional status and patient-rated chemotherapy-induced distress levels and relationships between other variables and nutritional status and distress. These programs also automatically produced tables, charts and graphs that were easy to understand. These, among others, would include the correlation coefficient (or "r"), the percent of variation in one variable that is related to the variation in the other (r squared). Pearson Correlation is used to measure the relationship between two quantitative variables, i.e. B.M.I. and distress. A correlation close to -1 indicates a strong negative relationship. A correlation close to 1 indicates a strong positive relationship. A correlation close to 0 indicates no relationship at all. Statistical significance would also indicate whether a correlation identified is due to chance (direct conversation with the statistician, 2009). Apart from those, the most common statistics would also be collected, i.e. percents, medians and means. I also searched for possible relationships between B.M.I. and Distress with various other variables which emerged from the data collection, namely patients' use of nutritional supplements, the strength of the chemotherapy, patients' use of steroids. These were compared and ANOVA testing carried out to identify any possible statistically significant relationships.