Physiological and Psychological Effects of Aromatherapy Massage on Critically Ill Patients

Thesis submitted in accordance with the requirements of the University of Liverpool for the degree of Doctor of Philosophy by Nicola Alaine Olleveant

July 2003

ABSTRACT

Aromatherapy is an increasingly popular but largely unresearched therapy, which uses essential oils for therapeutic effect (Tate 1997). The aims of the study were to evaluate the effects of massage only and aromatherapy massage compared to a control group, on both physical and psychological variables of patients who were critically ill in an intensive care unit. A randomised controlled trial methodology using three groups (no intervention, massage only or aromatherapy massage) was utilised. A foot and leg massage was given with or without essential oil of bergamot and was compared to those patients who had received no intervention. Patients received the intervention every third day of their stay in the intensive care unit. Outcome measures used to assess physiological variables were heart rate, blood pressure, respiratory rate, levels of analgesia and levels of anaesthesia. Psychological variables of anxiety and depression were measured using the Hospital Anxiety and Depression Scale (Zigmond and Snaith 1983) and quality of life variables were measured using the Short Form 36 (Ware and Sherbourne 1992) at discharge from intensive care and again one month later. Comprehensive statistical analysis was undertaken using MANOVA, ANOVA, Chi-Square, Kruskall Wallis and logistical regression to compare the groups. The statistical significance was set at the conventional 5% level.

There appeared to be no effects on heart rate, systolic blood pressure and respiratory rate but the diastolic blood pressure was significantly lower ($p=0.05$) four hours after a second aromatherapy massage compared to the other groups. There was also a significant reduction ($p=0.05$) in the number of patients who had received aromatherapy massage who required moderate to high doses of analgesia compared

to patients in the massage only or control groups on the day following the massage. Also one hour after the first intervention there were more patients who had received an aromatherapy massage who were classed as being asleep compared to patients who had received a massage or no intervention. There were no significant results pertaining to the psychological data. Tentative suggestions have been made of some effects due to the aromatherapy massage, however it is acknowledged that further work in these areas to substantiate these findings is necessary.

It has been suggested that the use of a randomised controlled trial to investigate complementary therapies is unsuitable (Canter 1992, McGourty 1993) however this study found that the use of a randomised controlled trial methodology was a valid and reliable design to use and was suited to the intensive care environment.

Further work examining aromatherapy should use single oils and no more than a two-group design which included some qualitative methodology in an attempt to capture effects of therapies which may be discrete. The use of properly conducted case studies would add valuable evidence to the literature regarding aromatherapy.

ACKNOWLEDGEMENTS

This research was undertaken in the Department of Clinical Psychology, University of Liverpool. It was commenced on a part-time basis whilst working as a sister on the Intensive Care Unit at the Royal Liverpool University Hospital and completed during a career break from being a nurse tutor at Manchester University. The project was funded through various bodies including, the Intensive Care Directorate, the Hospital Charities Board, the Florence Nightingale Trust, the District Health Authority, Manchester University and a training fellowship from the NHS Executive (North West).

I am indebted to my supervisors Dr Gerry Humphris, Department of Clinical Psychology and Dr Brenda Roe, Department of Gerontology, for their lengthy and constant supervision, support and valuable guidance in the completion of this work.

I am extremely grateful to my family and friends and professional colleagues for their constant encouragement and valuable support

I am ever grateful to Mr Carl Dodd and Dr Robert Wilkes whom gave me the opportunity to undertake this work and without their help, support and encouragement this thesis would never have happened.

This study could not have been completed without the help of the team of nurses who undertook the massages and all the other nurses who were involved with data collection. I am grateful to Pam Shepard who assisted in the formation of ideas regarding the aromatherapy massage. I am also thankful to all the staff of the intensive care unit, Royal Liverpool University Hospital, Liverpool, for their help and co-operation, without which this study could never have been successfully completed.

My sincere thanks to all the patients who have participated in this study.

CONTENTS

LIST OF TABLES

LIST OF GRAPHS

LIST OF FIGURES

1 INTRODUCTION

The use of massage and aromatherapy in health care has undergone a steady increase during the last fifteen years. It has been used in various contexts such as care of the dying (Byass 1988, Passant 1990), paediatric care (Field et al 1987, Scafidi et al 1990), cardiac nursing (Bauer and Dracup 1987, Buckle 1993), and for various conditions such as constipation (Emly 1993), insomnia (Hardy 1991, Williams 1991) and pain relief (Dale and Cornwell 1994, Turton 1989).

There has been an increasing number of nurses utilising complementary therapies in their work (Corner et al 1995, Wilkinson 1999, Ersser et al 1999, Hayes and Cox 2000). However, there is limited evidence to substantiate the benefits of these therapies and this has limited the capacity to practice these therapies in an evidence based health care system. In an attempt to address the lack of evidence there has been an increasing development of research, which has highlighted new problems such as inappropriate research methodologies (McGourty and Hotchkiss 1993) and inaccessibility to funding (House of Lords Select Committee 2000). There has been criticism from orthodox practitioners (BMA 1986) regarding the use of complementary therapies because there is little empirical evidence to support their use.

Surveys of the use of complementary therapies have demonstrated their increased use (Moore et al 1985, Murray and Sheperd 1988), and their acceptance into health care (Wharton and Lewith 1986, Anderson and Anderson 1987). Consequently there has been a growth in the numbers of complementary practitioners and users of their services (Fulder and Munro 1985, Thomas et al 1991). However due to this rapidly expanding market, concerns have been raised regarding standards of training, the effects of treatments and accountability (Rankin Box 1991).

This research was undertaken to determine if aromatherapy massage is an effective and feasible therapy to introduce to the care of critically ill patients. The study aimed to determine if aromatherapy massage would have relaxing effects on patients in intensive care by altering physiological and psychological variables. Anecdotal and empirical literature was systematically reviewed and a randomised controlled trial was undertaken to examine the effects of aromatherapy massage in critically ill patients. Randomised controlled trial methodology was employed to address the critics of research evidence examining complementary therapies, by undertaking a 'gold standard trial' (Richards et al 2000) in an attempt to produce clear evidence regarding the use of massage only and aromatherapy massage in critically ill patients.

This thesis has collated existing studies, which have examined the role of massage and aromatherapy massage in health care and differentiated between anecdotal and empirical studies to provide evidence of any findings. It provides an in-depth analysis of the effects of massage only and aromatherapy massage on both physiological and psychological parameters for patients who are critically ill.

OBJECTIVES

1. To test the effects of massage only and aromatherapy massage on physiological variables of heart rate, blood pressure and respiratory rate in critically ill patients in an intensive care unit, in a randomised controlled trial.

2. To test the effects of massage only and aromatherapy massage on the amounts of anaesthesia and analgesia administered to critically ill patients.

3. To determine the effects of massage only and aromatherapy massage on the occurrence of anxiety and depression following recovery from a critical illness.

4. To investigate the relationship between massage only and aromatherapy massage, and patients' quality of life following recovery from a critical illness.

5. To determine the longer-term effects of massage and aromatherapy massage on anxiety, depression and quality of life in critically ill patients, one-month post discharge from intensive care.

The study was undertaken part time over an eight year period. Literature searching and reviews has been continuous throughout this time. Data collection took three and a half years, using a sample population of critically ill patients and a comprehensive data analysis took two years. The results and findings are presented within the thesis and a final discussion has brought together all the work, finishing with conclusions and key recommendations for practice.

2. THE RESEARCH LITERATURE

Complementary therapies have become an interesting adjunct to traditional medicine over the past twenty years (Wafer 1994), with the public and health care workers demonstrating an interest in the use of these unorthodox remedies (Fulder and Munro 1985, Thomas et al 1991). This increased interest has resulted in many questions being raised regarding the validity of treatments, such as homeopathy, osteopathy, massage and aromatherapy, and their position in a traditional model of medicine. Little empirical work has been undertaken to substantiate many of the claims made by unorthodox practitioners and patients they have treated, and few practitioners of complementary therapies have undertaken common training which has resulted in no universal standards of ability to practice. This has led to scepticism regarding the benefits and use of complementary therapies as commodities in health care, and has resulted in a need to collate and redefine future areas of study. It has also highlighted the need to standardise training and professional qualifications.

This review has examined the introduction of complementary therapies into health care and defined the terms 'complementary medicine' and 'complementary therapies'. A systematic review of both published and unpublished literature was undertaken and has included both empirical and anecdotal literature, to produce a structured and focused review. The review examined the introduction of complementary medicine into Britain and determined a working definition of complementary medicine. This was followed by an historical analysis of the literature and a review of the definition and use of massage and aromatherapy, including an in-depth critical analysis of all anecdotal and empirical literature relating to both massage and aromatherapy massage in health care. The outcome measures used in the empirical studies in both massage and aromatherapy massage were also collated and reviewed.

2.1. Literature search and analysis

2.1.1. Method of searching the literature

A thorough search of the relevant published and unpublished literature in English was made including studies published from 1988 to 2002. The databases utilised in the search included, Medline, CINAHL (cumulative index to nursing and allied health literature), the Complementary Therapies Database, Bodyworks Index, AHMED (allied and complementary medicine), EMBASE, BIOMED, BNI (British nursing index), Cochrane library, Psych. Info, NRR (national research register). The databases were examined using the terms massage, aromatherapy, complementary medicine and complementary therapy, alternative medicine and alternative therapy, and essential oils. In addition, cross-referencing which cited references was also employed and references published before 1988 included. Many of the references had to be secured through inter library loan due to them being published in obscure journals not routinely kept at university libraries. In an article published in 1995, Ersser (1995) presented a resume of the problems associated with accessing literature relating to complementary therapies. The problems highlighted included, limited numbers of research articles for access, nurses limited ability to determine if the research is of good quality and the scarcity of research articles published on popular nursing databases which are readily available to nurses, such as CINHAL. Vickers and Rees (1995) also documented problems encountered whilst searching databases for evidence, highlighting the difficulties which arose when attempting to access literature relating to complementary therapies. They found that keywords used to access literature did not result in the production of the evidence required. They suggested that any searches are limited by a fee-paying service for access to the CISCOM database which is managed by the Research Council for Complementary Medicine. This contains information that is classified so that researchers can limit their searches using different categories. The cost of this service depends on the nature and size of the search.

Due to the problems with accessing the literature (Ersser 1995, Vicker and Rees 1995), The House of Lords Select Committee (2000) recommended that the NHS Centre for Reviews and Dissemination work with the Research Council for Complementary Medicine group (RCCM), the UK Cochrane Centre and the British Library to develop a comprehensive and publicly available source of information relating to complementary and alternative medical research.

Unpublished literature was accessed by writing to the DHSS database, telephoning intensive care units throughout Britain, visits to conferences and by hand-searching the index of theses.

References were included in the review if they were;

i) published/written up between 1980 and the end of 2002

ii) written in English

iii) related directly or indirectly to the use of complementary therapies including all studies involving the use of massage or aromatherapy massage. Studies using aromatherapy which did not include massage were also included if they were using aromatherapy as a method of relaxation and they utilised outcome measures relating to sedation, pain, anxiety, depression or quality of life.

Studies relating to other forms of complementary medicine were excluded due to them being unrelated to the area chosen for research and time constraints.

2.1.2. Questions to Guide the Literature Review

A series of questions were compiled to guide the collection of literature, focus the review and direct the need for further research. The articles selected for inclusion were those likely to answer questions asked of the literature, therefore enabling areas where further research is required to be highlighted. The questions are listed in Table 2.1.

Table 2.1 Questions to Guide the Literature Review

No.	QUESTIONS
1	What are complementary therapies?
2	Are there differences between the terms complementary medicine and alternative therapies?
3	What proportion of the population utilises complementary therapies?
4	Which therapies are offered and by whom?
5	What are the professional requirements and legal constraints to the practice of complementary therapies?
6	What is massage, and what proportion of the population utilises this therapy?
7	In which areas has massage been successfully and unsuccessfully used?
8	What is aromatherapy, and what proportion of the population utilises this therapy?
9	In which areas has aromatherapy massage been successfully and unsuccessfully used?
10	Which methodologies are most appropriate for evaluating the effectiveness of complementary therapies?

2.1.3. Handling the Literature

A total of 315 references were generated, from a total of 67 journals. These were divided into three groups of literature:

i) definitions of complementary/alternative medicine/therapy including studies of prevalence of use.

ii) literature relating to the use of massage

iii) literature relating to the use of aromatherapy massage

The literature within each of the groups was subdivided into empirical and anecdotal literature, and was reviewed separately. All studies were subjected to rigorous review and were tabulated. Empirical studies were divided into speciality and outcome measures, and were reviewed in these contexts. The literature was examined in this way in an attempt to address problems within the literature of nurses not critically analysing articles. Vickers (1997) suggested that knowledge claims related to massage and aromatherapy are poorly presented, and much of the evidence used to substantiate the effects of massage and aromatherapy do not use primary literature.

2.2. Complementary Therapy in Britain

This section has reviewed the introduction of complementary therapies into Britain. Some commonly used terms were examined including the terms complementary or alternative, and the terms therapy or medicine. The historical development of complementary therapies was examined and some commonly used therapies described. Empirical studies undertaken regarding the prevalence of the use of complementary therapies were reviewed and tabulated. Research methodologies appropriate to determining the effectiveness of complementary therapies were discussed. The section concludes by highlighting the professional implications for practice, including a review of current training in complementary therapies, and a discussion of whether practice constitutes an extended role for health care workers. Guidelines for safe practice were also reviewed.

2.2.1. Classification of Complementary Therapies

Complementary therapies are one of the most popular terms used to describe those therapies, which are used as a complement or an alternative to orthodox medicine (Fisher and Ward 1994). Other terms include non-conventional, unorthodox, alternative, natural or fringe medicine or therapies. In 1983 the World Health Organisation (Bannerman et al 1983) defined alternative medicine as all forms of health care provision which 'usually lie outside the official health sector'. In Britain there are over sixty types of 'practice' which this term would encompass including osteopathy, hypnotherapy and healing (BMA 1993).

A survey of general practitioners (Anderson and Anderson 1987) which asked subjects to define alternative medicine, found that 54% (N=222) of them defined it as 'additional to western medicine', 'not taught at medical school' or 'not available on the NHS'. Sixteen percent of respondents had defined alternative medicine as 'unscientific'.

Discrepancies were apparent in defining the differences between the words complementary and alternative. The BMA (1993) defined complementary therapies as those, which can work alongside and in conjunction with orthodox medical treatments, for example, yoga, the Alexander technique, acupuncture, osteopathy, chiropractic, massage and aromatherapy. In contrast, they defined alternative therapies as those which are given in place of orthodox medical treatments, for example herbal medicines used as allopathic drugs. Gates (1994) pointed out that complementary therapies did not seek to replace the range of treatments available at the disposal of health care practitioners, and therefore in doing so agreed with the views of the BMA.

Changes have occurred in the use of the term alternative to complementary and this change was welcomed by the medical profession (Fisher and Ward 1994). In 1993 the BMA indicated a shift in their attitude. They chose to use the term non-orthodox, rather than alternative or complementary. Non-conventional therapies were defined as: 'those forms of treatment which are not widely used by the orthodox health care professions and the skills of which are not taught as part of the undergraduate curriculum of orthodox medical and paramedical health care courses'. Prior to this time the BMA (1986) had produced a document which was found to have a negative bias towards alternative therapies, and this resulted in pressure from various groups (The Research Council for Complementary Therapies, RCCM) to re-examine their views.

Rankin-Box (1991) suggested a simple way of categorising the differences between the terms medicine and therapy. She recommended that three categories exist and that some therapies represent systems of medicine such as acupuncture, homeopathy and herbalism, some therapies are diagnostic eg iridology, whilst massage and aromatherapy are primarily therapeutic in nature.

The Select Committee on Science and Technology (2000) proposed three groups of complementary or alternative therapies (CAM) in order to categorise them. Group one included the most organised professions, for example acupuncture, group two contained those therapies that most clearly complemented conventional medicine for example aromatherapy and massage, whilst those therapies in group three lacked any credible evidence base and were unsupported therapies with no convincing research evidence of their efficacy, for example iridology.

Recently Furnham (2000) undertook a survey of 589 members of the public to determine how the public classify complementary therapies. He found that whilst experts tended to classify therapies into structural, biomechanical or psychological, the public classified them primarily in terms of familiarity and perceived effectiveness. The public also did not classify in terms of the therapies mechanism of action, process, history or cost and Furnham (2000) suggested that this implied they have relatively little knowledge of CAM therapies.

Many of the studies published used different words to describe complementary therapies and this may have affected the responses elicited. The term used in this review was complementary therapies, as this was thought to be the most appropriate term to describe massage and aromatherapy.

The complementary therapies, which have been mentioned in this review, are briefly described below.

ACUPUNCTURE.

There are two main forms of acupuncture, the first being a traditional branch of Chinese medicine, involving the insertion of needles into the body and the selection of acupuncture points, for therapeutic purposes. Another form of acupuncture involves a modified form of acupuncture, placing greater emphasis on analgesic effects. Stainless steel needles are inserted perpendicular or obliquely to various depths, depending on prescription. The point is then usually stimulated by rotating the needle or applying a periodic electric current for ten to twenty minutes at a time (BMA 1986). Conditions treated include nervous tension, asthma, bronchitis, arthritis, cystitis, Bells palsy, skin conditions, pre menstrual tension, chronic pain, hay fever, migraine, depression and to induce anaesthesia. The patients' general practitioner (GP) is usually informed, and referral can be through a GP, though this is not always necessary. There is an ethical code of conduct. The Council for Acupuncture undertakes research in this field and it can be found in peer-reviewed journals (Vincent and Richardson 1987).

AROMATHERAPY.

Aromatherapy involves massage with essential oils or the use of essential oils delivered externally in other ways for example via air fresheners or added to the bath. It is usually used for stress and stress related disorders such as headaches and indigestion. The patients' GP is usually informed, and referral can be through a GP though this is not necessary. An ethical code of conduct exists. The International Federation of Aromatherapists undertake research, but this is not generally found in peer-reviewed journals, and therefore does not undergo the scrutiny of a panel of readers to determine valuable research (BMA 1993).

CHIROPRACTIC.

Chiropractic involves joint adjusting procedures, manipulation, soft tissue massage, exercises and the application of corsets, splints and supports. Emphasis is placed on the use of spinal X-rays for the diagnosis of mechanical problems. Any subject who has a musculo-skeletal related problem uses it. Referral is through a GP and therapists are actively encouraged to inform the GP of treatment. An ethical code of conduct exists. Research is undertaken by the British Chiropractic Association, and has been published in peer-reviewed journals (Kane et al 1974, Meade et al 1990).

HERBALISM.

This is a system of treatment in which various parts of plants are used to restore function and to treat symptoms. It is based on the idea of promoting the bodies own homeostatic mechanisms to restore health (BMA 1993). Herbal medicines are usually prepared from plant materials and therefore contain a range of substances, not one active constituent, and this is thought to be beneficial as it is believed that the other ingredients may potentiate the effect and reduce the danger of side effects. The medicines are administered in small doses and are discontinued once the desired effect is reached, thus reducing the chance of side effects (BMA 1986). It is used to treat mainly chronic illness such as arthritis, skin conditions, stress, migraines and chronic infections. General practitioners are not routinely informed of any treatment and referral is rarely by GP. A comprehensive code of ethical conduct exists. Research is undertaken by the National Institute of Medical Herbalists which is linked to the centre of Complementary Health Studies at Exeter University. Research is published in peer-reviewed journals (BMA 1993).

HOMEOPATHY.

Homeopathy involves the treatment of patients by administering highly diluted forms of natural substances that in a healthy person would bring on symptoms similar to those which the medicine is prescribed to treat (BMA 1993). A wide range of acute and chronic, physical, mental and emotional illness are treated. An ethical code of conduct exists. Research is undertaken by the Society of Homeopaths, which is peer reviewed.

IRIDOLOGY.

This is a method of diagnosis based on studying the markings on the irises of the eyes and observing changes in them. The patients' eye is examined closely with a torch and magnifying glass, whilst the therapist notes the colour, texture and other features of the iris. Diagnosis is based on the belief that the organs and systems of the body are reflected onto the iris (BMA 1986). A small number of patients are referred by GP, who is only informed of this alternative treatment at the patients request. An ethical code of conduct exists. The British Society of Iridologists undertakes research, but studies undertaken are only published in their own journal and are not peer reviewed (BMA 1993).

MASSAGE.

Massage involves the rubbing and kneading of areas of the body, normally using the hands. It is mainly used to treat back complaints, headaches, stiffness, and tension related complaints. General practitioners' do not usually refer patients. Patients are usually advised to inform their GP of any treatment. An ethical code of conduct exists. No research is undertaken by the main organisation, The London College of Massage (BMA 1993).

NATUROPATHY.

Naturopathy is based on a belief that the body is its own inherent healing force, which is believed to be unique depending on heredity factors, constitution and life history. There is a great emphasis on creating the most suitable conditions for the body to heal itself. There is an emphasis on the use of natural substances, and great attention is paid to diet. It is used to treat sore throats and bronchitis and is used to treat functional complaints such as digestive disorders. Treatment usually takes the form of a change in diet and the use of supplements and vitamins (BMA 1986)

OSTEOPATHY.

This is a system, which involves both diagnosis and treatment the main emphasis of which is on conditions affecting the musculo-skeletal system. It uses predominantly gentle manual and manipulation methods to restore and maintain proper biomechanical functions. Referral is usually by a GP, who is sometimes informed of the treatment. An ethical code of conduct exists. The General Council, Registrar of Osteopaths and the College of Osteopaths Practitioners Association undertakes extensive research, which is peer reviewed (BMA 1993).

REFLEXOLOGY.

Reflexology utilises compression and massage techniques using reflex points in hands and feet. Reflexology claims to treat the whole person (BMA 1986). Referral is by GP, and the patient is advised to inform his or her own GP of any treatment. An ethical code of conduct exists. Research is undertaken, which is peer reviewed (BMA 1993).

2.2.2. Historical Perspectives

Complementary medicine such as acupuncture, Chinese medicine and herbalism have existed for thousands of years, and are thought to be ancient arts (Tisserand

1994). In Britain and across Europe over the last thirty years there has been an increasing interest in the use of complementary medicine (Halpern 1985, Visser 1991, Eisenberg et al 1993). Some professional groups for complementary therapies existed in the 19th century, such as the National Institute of Medical Herbalists founded in 1864 and the Faculty of Homoeopathy founded in1844. By the early and mid 20th century these professional groups were becoming more prominent for example the British Chiropractic Association (1925), the General Council and Register of Osteopaths (1936), the College of Osteopaths (1946), and the British Acupuncture Association and Register (1961).

By the 1960s the publics' interest in the United Kingdom in complementary therapies had grown. It was suggested that this was in part due to the side effects of the drug thalidomide and the public's disillusionment with modern medicine, as it had not become the panacea that was promised to be and the public began to view prescriptions with more apprehension (Baldwin 1991, Mills 1993). The population recognised the limitations of orthodox medicine (Thomas et al 1991). Mills (1993) implied that a change in generation emerged and the younger generation began to regret the loss of the older community and cultural values, which led to a clear swing to new approaches to life becoming evident. The word 'holistic' became prominent and new interest in the cultures of the Orient, India and China emerged. Also, in the 1960s communist China became less isolated from the USA and American doctors visited China to see their health care system. This led to doctors returning to America with stories of the use of acupuncture for pain relief and analgesia. When these modern ideas were broadcast on television the new idealists grasped what they regarded as an exciting opportunity.

In the late 1960s attempts were made to unify alternative medicine and through these efforts the movement named 'The British Federation of Practitioners of Natural Therapeutics' emerged. A research society for naturopathy established itself as pioneers of complementary medicine. The 1970s saw a rapid rise of recruitment to training courses and a proliferation of new colleges and professional bodies emerged (Coward 1989). Most of these developments were in areas where medical science, diagnostic and clinical skills were not demanded, mainly hypnotherapy, reflexology, aromatherapy, and other manual and mind/body therapies. By the end of the 1970s many groups and practitioners existed which confused the public about training and standards. Many of these problems still exist today, with ongoing debates regarding the standard of training, and the extent to which training should be undertaken. See section 2.4. Professional Implications for Practice, pgs. 42-45.

The increasing interest in complementary therapies resulted in the Royal College of Nursing (RCN) establishing a special interest group in 1994 to provide a focus for the use of complementary therapies within nursing practice. This group has steadily increased in membership from 650 in 1994 to over 4000 in 2000 (RCN 2001).

2.2.3. Prevalence of Complementary Therapies

Surveys have been undertaken to determine the prevalence and use of complementary therapies, by examining the views of general practitioners (table 2.2), nurses (table 2.3), complementary medicine practitioners (table 2.4) and consumers of health care (table 2.5).

Five studies used a survey style methodology to examine the views and use of complementary therapies of general practitioners, table 2.2. The terms used to define complementary therapies differed in these studies and therefore the definitive word used in each study has been stated as this may have affected the responses obtained. All the studies showed that some GPs (12-38%) had received some training in commonly used complementary therapies in order to answer general questions from patients. The studies also suggested that GPs would like additional training in homeopathy, acupuncture, chiropractic and osteopathy. However, it was interesting that even though 59% of GPs knew little about complementary therapies they thought it would be useful to their patients (Wharton and Lewith 1986). The studies demonstrated that 13-16% of GPs practised some form of complementary therapy with patients in their practice. Adverse effects were reported in two studies (White et al 1997, Perry and Dowrick 2000). These included patients feeling worse after the therapy to more serious complications such as paraplegia, fractured vertebra and fractured neck of femur.

These five studies examined the views and uses of GPs regarding complementary therapies. General practitioners are usually the first point of contact patients have when they are ill. However these surveys demonstrated that GPs do not use complementary therapies to a large extent in their practice. This is in contrast with the surveys examining patients' views and uses of therapies, which suggested that patients often attended a complementary therapy practitioner without the knowledge of their GP. White et al (1997) found that GPs did not feel confident to discuss complementary medicine with their patients.

Table 2.2 Surveys of General Practitioners Views and Uses of Complementary Medicine

Author	Design	Sample	Response	Definitions	Findings
Reilly (1983) Scottish National Conference	Survey	Convenience sample of GP trainees N = 100	N = 86 (86%)	Term used = AM - one which is usually excluded from medical undergraduate curriculum at any one time	21% (n=18) doctors used at least one AM 81% (n=70) doctors wanted training in alternative medicine 36% (n=31) doctors had referred patients for treatment, 14% (n=12) to non-medically qualified alternative practitioners
Wharton and Lewith (1986) Avon	Survey	Random sample of GPs N = 200	N = 145 (73%)	Term used = CM - limited to those well known definable techniques ie osteopathy, chiropractic, acupuncture, hypnosis, faith healing, herbal medicine and homeopathy	38% (n=55) had received some training in CM 15% (n=22) wanted training 76% (n=110) had referred patients to medically qualified colleagues 72% (n=104)had referred patients to non-medically qualified colleagues 93% (n=135) believed that CM needed statutory regulation 3% (n=4) thought CM should be banned
Anderson and Anderson (1987) Oxfordshire	Survey	Convenience sample of GPs N = 274	N = 222 (81%)	Term used = AM 54% defined it as; additional to western medicine not taught in medical school not available on the NHS	31% (n=69) believed they had a working knowledge of AM 12% (n=27) had received training 42% (n=93) would like further training 16% (n=36) practised AM 59% (n=131) referred patients to an AM practitioner
White et al (1997) Devon and Cornwall	Survey	All primary care GPs working in the area N = 972	N = 461 (47%)	Term used = CM - included acupuncture, manipulation, homeopathy, hypnotherapy, medical herbalism, reflexology, aromatherapy	68% (n=314) had used CM in the previous week 16% (n=74) of doctors practised some form of CM 25% (n=115) GPs had referred patients in the previous week 49% (n=229) thought it was important to learn more about CM More than ½ recommended that the most effective therapies should be available on the NHS ie homeopathy, acupuncture, chiropractic and osteopathy 44% (n=176) reported adverse effects
Perry and Dowrick (2000) Liverpool	Survey	GPs working in a socially deprived area N = 252	N = 131 (52%)	Term used = CM - included acupuncture, osteopathy, chiropractic, homeopathy, hypnotherapy, aromatherapy	56% (n=74) had been involved with therapies through their patients in the previous week; 13% (n=17) had treated themselves, 31% (n=41) had referred and 38% had endorsed one or more therapy Most commonly used therapies should be available on NHS ie homeopathy, osteopathy, acupuncture and chiropractic 49% (n=64) would like further training 62% (n=81) reported successful outcomes 21% (n=28) reported adverse reactions, mainly from medical herbalism

KEY: CM=complementary medicine, AM=alternative medicine.

Perry and Dowrick (2000) found that even though GPs referred patients to complementary medical practitioners they had little knowledge of the therapies content or validity. However the studies found that the interest expressed by general practitioners to be high. Even though these studies suggest an interest in complementary medicine by doctors, a report published in 1986 by the BMA was bereft of any expert evidence and the negative tone of the report was immediately subjected to public and media ridicule (BMA 1986).

These studies also highlighted the gap between the British Medical Associations' understanding of the need for training in complementary therapies and the willingness from GPs to undertake further training in order to meet a need expressed by their patients. GPs need to have an understanding of which CAM therapy is useful for what illness and which therapies have an evidence base and are proven to be effective.

Two studies were retrieved, which reported the use of complementary therapies by the nursing profession, table 2.3. In 1996 Trevelyan reported the findings of a survey undertaken by the Nursing Times of its readers and Rankin-Box (1997), surveyed nurses use of complementary therapies using a convenience sample of nurses who were members of the Royal College of Nursing Complementary Therapy Forum.

Table 2.3 The Use of Complementary Therapies by the Nursing Profession

Author	Design	Sample	Response	Definitions	Findings
Trevelyan (1996)	Survey	N = unknown Nursing Times readers	N = 393	CT – not defined	Most commonly used therapies include massage, aromatherapy, reflexology, therapeutic touch, homeopathy and acupuncture
Rankin-Box (1997)	Survey	N = 1662 Convenience sample of nurses who were members of the RCN CTF	N = 178 (11%)	CT – not defined	Six principle therapies were practised, massage, aromatherapy, reflexology, relaxation, visualisation and acupuncture Most commonly used in community, palliative care and oncology Nurses were found to practice CT much less than previously assumed

KEY
RCN CTF – Royal College of Nursing Complementary Therapies Forum
CT – complementary therapies

The results suggested that nurses are using complementary therapies much less than previously assumed and they tend to practice in those therapies belonging to group two (therapies which complement conventional care). The study by Rankin-Box (1997) should be viewed with caution due to the limited response rate (11%). A much larger national survey would be a useful to evaluate the extent of nurses' use of complementary therapies and their views of using them.

Two studies were undertaken which examined the prevalence of practitioners of complementary therapies, table 2.4. The first study published in 1985 (Fulder and Munro 1985) entitled 'complementary medicine in the United Kingdom; patients, practitioners and consultations', demonstrated that there was a growing and substantial subsidiary health care system, which complemented rather than competed with conventional medicine.

A second study (Thomas et al 1991) investigated the use of orthodox and non-orthodox health care and their pattern of use by means of a large postal survey. This study excluded many therapies that were thought to be non-orthodox and varying definitions of these therapies resulted in differences in the data collected. Non-orthodox practitioners undertook four million consultations, which was equal to 1 in 55 patient consultations with a general practitioner in the NHS.

Table 2.4 Surveys of the prevalence of practitioners of complementary therapies

Author	Design	Sample	Response	Definitions	Findings
Fulder and Munro (1985) 7 areas of Britain	Survey – questionnaire	Convenience sample of practitioners of CM N = 232	N = 136 (59%) 95% Oxfordshire 97% Cambridgeshire 22% Penrith	Term used: CM = a lay practitioner who makes themselves available to diagnose and treat members of the public	There are 12 CM practitioners per 100,000 of pop., equivalent to 26.8% of GPs 2.4% of population receive courses of treatment/year 42% practised more than one therapy 50% had attended a college course Average course of treatments = 9.7 visits to the practitioner Two thirds (70%) of patients were female aged 21-60, from higher social classes Consultations are 6 times longer than with GP
Thomas et al (1991) United Kingdom	Survey – questionnaire	Convenience sample of practitioners of NOHC N = 2152 Corresponding group of patients who had attended one of the practitioners N = 3082	Practitioners, N = 1575 (73%) Patients, N = 2473 (80%)	Term used: NOHC = care provided by qualified, non-medical practitioners belonging to professional associations that regulate the practice of their members	78% of patients were seen by non-orthodox practitioners with a musculo-skeletal problem Two thirds of patients were female 1 in 3 patients had not received previous conventional care 22% of patients had seen their GP in the previous 2 weeks 64% of patients reported receiving orthodox treatment first 24% were in receipt of concurrent conventional treatment

KEY; CM=complementary medicine, NOHC=non orthodox health care

Six studies utilising survey methodology were found which examined consumers' interest and demand for complementary therapies, table 2.5. In the mid to late 1980's, literature was reporting the publics' utilisation and demand of complementary therapies (Halpern 1985, Moore et al 1985, Consumers Association 1986, Murray and Shepherd 1988, Furnham 2000). The jointly commissioned piece of research entitled the Marplan Survey (Halpern 1985) was undertaken between the Health and Social Service Journal, and the National Association of Health Authorities to determine consumers' views of the NHS and a further study undertaken in 1985 (Moore et al 1985) examined the reasons why people sought alternative medicine.

The survey methodology used in these studies was able to generate considerable evidence to demonstrate an interest and demand for the use of complementary therapies by using large random sample sizes (n=1942, Consumers Association 1986; n=1204, Ernst and White 2000) and obtaining good response rates (72%, Murray and Shepherd 1988 to 100%, Halpern 1985, Consumers Association 1986). All of these studies included more in-depth information gained by using questionnaires (Moore et al 1985, Consumers Association 1986, Murray and Shepherd 1988, Furnham 2000) and interviews (Moore et al 1985, Halpern 1985, Ernst and White 2000) on selected respondents.

Consumers were interested in using CAM for many reasons including dissatisfaction with conventional medicine and further in-depth information (Murray and Shepherd 1988) found that patients expressed feelings of being treated as individuals and being given the opportunity to present their health problems in the way they perceive them.

Table 2.5 Surveys of Consumers Views and Uses of Complementary Medicine

Author	Design	Sample	Response	Definitions	Findings
Moore et al (1985) Southampton	Survey – questionnaire and interview 8 weeks later	Convenience sample of adults attending a centre for AM n = 65	N = 56 (86%)	Term used; AM Not defined	Consumers; social class 11, married, female, aged 26-50 Complaints treated; pain 54%, allergies 18%, psychological 5% Referrals; 22% via GP, 98% self referred, 96% attended due to failure of conventional medicine
Halpern (1985) Britain Marplan Survey	Survey – interview	Random, adults > 15 n = 1500	N = 1509 (101%)	Term used; AM Eg acupuncture, osteopathy, homeopathy	Consumers; 26% were using AM, 16% acupuncture, 16% homeopathy, 24% phytotherapy or herbalism Complaints treated; NA Referrals; NA
Consumers Association (1986) Which members	Survey – questionnaire	Random sample of 28,000 readers N = 1,942	N = 1,942 (100%)	Term used; CM Eg acupuncture, osteopathy, homeopathy	Consumers; 31% said they had been cured of their problem and 51% said the condition had improved, 74% said they would use CM again Complaints treated; 71% pain or joint problems, 15% psychological Referrals; 81% has visited their GP first 81% visited because they were dissatisfied with conventional medicine
Murray and Shepherd (1988) South London	Survey – questionnaire (1st phase)	Patients in a general practice N = 5700	N = 77 (1%)	Term used; AM Eg osteopathy, homeopathy, acupuncture	Consumers; NA Complaints treated; back pain, asthma, cystitis Referrals; self referral, often after a specialist referral
Ernst and White (2000) Devon and Cornwall	Survey – telephone interview	Random, British adults N = 1204	N = 1204 (actual response rate unknown)	Term used; CAM	Consumers; 20% used CAM in previous year Used for; perceived effectiveness, a positive inclination and relaxing effects Users spent about £13.62 per month Annual national expenditure = £1.6 billion
Furnham (2000) Southern England	Survey - questionnaire	N = ? Tot. target pop. unknown Random, Adults	N = 589	Term used; CAM	Consumers; 61% tried massage, 50% tried relaxation, 48% tried aromatherapy, 36% tried herbal medicine Used for; NA More likely to use a CAM therapy if they have heard of it or know how it works

KEY; NA-not available CM-complementary medicine
AM-alternative medicine CAM-complementary or alternative medicine

Quotations such as ‘it’s the human factor that’s missing from the NHS, it’s too scientific’, ‘wholesome and holistic’ and ‘I felt like a million dollars. I’ve never had so much attention in my life’ all suggest dissatisfaction with parts of the NHS.

Patients visited Practitioners of complementary therapies for problems such as chronic pain, allergies and psychological problems and were willing to pay for treatments demonstrating their commitment to try alternative therapies. These studies show a willingness by the public to try alternative methods of treating their illnesses and their interest in CAM.

Some inconsistencies arose when comparing these studies, which may have been due to irregularities in the terminology that were used to define complementary therapies. Words that were used included complementary medicine (Fulder and Munro 1985, Consumers Association 1986 and Wharton and Lewith 1986), alternative medicine (Reilly 1983, Halpern 1985, Moore et al 1985, Anderson and Anderson 1987 and Murray and Sheperd 1988) and non-orthodox health care (Thomas et al 1991). This difference in terminology and definition prevents valid comparisons between these studies and only inferences can be suggested. Also obscure therapies highlighted in the report by Furnham (2000) such as autogenic training, ayurveda, ozone therapy, biochemical tissue salts, chelation and cell therapy demonstrated that people are unlikely to try CAM therapies which they had not heard about or do not know how they work.

However, even though many survey studies have now been undertaken, the health caring professions still are not convinced regarding the benefits of complementary therapies (Martin 1991). In 1993 the BMA remained dismissive regarding the use of complementary medicine, whilst studies being reported at the time showed that many health practitioners were becoming interested in complementary therapies. A new Department at Exeter University aimed to identify and collate the research evidence that complementary medicine is lacking (Mills 1994). The medical profession may find it difficult to believe in complementary therapies because there is a lack of evidence available compared to the amount of evidence produced for pharmaceutical drugs. This belief is passed on through published papers, "complementary medicine represents the medicine of the people, tied in with folklore and tradition and based on wisdom that was often passed down orally through generations" (Trevelyan and Booth 1993). Mills (1994) acknowledged that there are relatively few properly conducted clinical trials, but agreed that practice still takes place, and Ernst and White (2000) concluded their report by reiterating the urgency of scientific validation for the use of CAM. There needs to be further stringent research studies undertaken examining the effects of complementary therapies, to enable an effective database with credible research to demonstrate the positive effects of therapies and the diverse nature of different research methodologies which can be undertaken to achieve these results.

A recent study (NHS Confederation 1998) of complementary medicine in the NHS provided a central and independent source of management information on the provision and use of complementary medicine within the NHS. A wide range of health service professionals including GPs, dentists, a range of nurses, occupational therapists, physiotherapists and managers in Leicester were involved in a questionnaire survey and a further smaller sample were interviewed. The term complementary medicine was used in this study. More than 2,400 questionnaires were mailed. A total of 671 were returned of which 651 (97%) were used. All of the NHS staff groups surveyed used complementary medicine. Midwives were the highest-level users (34%, n=48), whilst dentists were the lowest-level users (6%, n=3). The most commonly used therapy was aromatherapy and the dominant users were midwives. Thirty one percent (n=43) of midwife respondents used aromatherapy. Four main reasons were identified for not using complementary medicine; a lack of knowledge of practitioners or therapists to whom to refer patients, lack of available funds, concern about the competence of complementary practitioners or therapists and lack of evidence as to the effectiveness of complementary medicine. The NHS Confederation (1998) concluded that the way forward for the NHS would need to be initiated from government funds, to ensure that issues such as effectiveness, training, qualifications, competence and funding are addressed. It could also lead to the development of policies, dissemination of good practice and could build links between the NHS and complementary medical organisations. This could facilitate the systematic and rational integration of complementary medicine into the NHS, having regard to its effectiveness, cost effectiveness and the benefits to patients.

2.3. Research Methodologies in Complementary Therapies.

There have been many claims that few properly conducted clinical trials have been undertaken in complementary therapies (Moser 1982, Byrne 1992, McGourty and Hotchkiss 1993). Many studies examining the effectiveness of complementary therapies do not conform to the same test requirements and standards demanded of orthodox medicine, and few therapies are tested according to principles of scientific method. Other tests of efficacy (which may be used to substantiate the use of complementary therapies such as subjective case reports) are thought to be invalid in the scientific community.

The mid to late 1980's saw the start of published literature regarding complementary therapies. Much of this was descriptive in nature and described numerous therapies that were available (Armstrong 1985, Wright 1989, Stevenson 1992). It was not until the late 1980's that there was a realisation of a distinct lack of research into these therapies and the first studies began to be undertaken (Hardy 1991). In the area of massage only, 23 studies were found. Fourteen utilised randomised controlled experimental methodology, eight used quasi-experimental methodology and one used a case study (table 2.6). Twenty-nine studies were undertaken in aromatherapy and ten of these have utilised randomised controlled methodology and eight have used quasi-experimental methodology (table 2.7). These tables have demonstrated the poor sample size utilised in many of the studies and the use of more than two study groups has enhanced this problem. None of the studies mentioned the use of a statistician for sample size calculation or the use of effect size. If randomised controlled trials are to be undertaken they must be good quality as this further compounds sceptics views of poor trials offering no scientific evidence.

Experimental research methodologies may not be an appropriate way of evaluating complementary therapies (Canter 1987, Janine Bell 1987). Aldridge (1989), Leibrich (1990) and Canter (1992) argued that problems have arisen because of a lack of appropriate research methodologies to examine holistic therapies.

Table 2.6 Methodologies utilised within Massage Studies

Methodology	Studies	Sample size	No. of groups	Total
RCT	Field et al (1987)	40	2	14
	White-Traut and Goldman (1988)	33	2	
	Weinrich and Weinrich (1990)	28	2	
	Scafidi (1990)	40	2	
	Field et al (1992)	72	2	
	Fraser and Ross Kerr (1993)	21	3	
	Groer et al (1994)	32	2	
	Corley (1995)	19	2	
	Sunshine et al (1996)	30	3	
	Field et al (1997)	20	2	
	Field et al (1998)	28	2	
	Richards (1998)	69	3	
	Ersser (1998)	32	2	
	Hulme et al (1999)	59	2	
Quasi-exp	Barr and Talitz (1970)	10	2	8
	Sims (1986)	6	2	
	Longworth (1982)	32	1	
	Bauer and Dracup (1987)	25	1	
	Fakouri and Jones (1987)	18	1	
	Tyler et al (1990)	173	1	
	Meek (1993)	30	1	
	Hayes and Cox (2000)	25	1	
Case studies	Farrow (1990)	30		1

Table 2.7 Methodology utilised in Aromatherapy Massage Studies

Methodology	Studies	Sample size	No. of groups	Total
RCT	Buckle (1992)	28	2	10
	Bell (1993)	30	3	
	Dale and Cornwell (1994)	635	3	
	Stevenson (1994)	100	4	
	Dunn (1995)	122	3	
	Wilkinson (1995)	51	2	
	Diego et al (1998)	40	2	
	Wilkinson et al (1999)	103	2	
	Basnyet (1999)	20	2	
	Saeki (2000)	10	1	
Quasi-experimental	Hardy (1991)	4	1	8
	Woolfson and Hewitt (1992)	36	3	
	Corner et al (1995)	52	3	
	Hudson (1996)	9	1	
	Lindsay et al (1997)	8	1	
	Brownfield (1998)	9	1	
	Clarke (1999)	21	1	
	Walsh and Wilson (1999)	4	1	
Case Studies	Wilkinson (1991)	1		4
	Williams (1991)	1		
	Brooker et al (1997)	4		
	MacMahon and Kermode (1998)	1		
Survey	Reed and Norfolk (1993)	38		1
Exploratory	Cawthorn (1991)	20		6
	Burns and Blamey (1994)	585		
	Cooper (1995)	30		
	Kite et al (1998)	58		
	Papadopoulos et al (1999)	6		
	Burns et al (2000)	8058		

Other methodologies can provide useful information and ground work for future scientific studies. Only two (8%) of the massage studies reviewed within this thesis used two different methodologies, whilst eleven (38%) of the aromatherapy studies used three different methodologies. The aromatherapy studies may have utilised a more varied methodology due to them being undertaken more recently than the massage studies and have therefore been able to utilise the previous work.

McGourty and Hotchkiss (1993) produced the only major source of literature regarding the use of randomised controlled trials in complementary medicine. They reviewed the literature regarding research methodologies employed in complementary therapies and agreed that different methodologies may be required to evaluate 'a system of medicine which is holistic in nature'. They suggested a number of reasons as to why clinical trial methodology was not appropriate to complementary therapies:

i. Alternative theoretical framework

Researchers need to be aware of alternative theoretical frameworks in the initial stages of designing the research ie when constructing the research questions, designing the control groups, selecting variables etc. They need to have less definite preconceptions with regards to the theory they are testing.

ii. Different diagnostic approaches

Holistic approaches to research allow a wider range of data to be integrated into the patient diagnosis, unlike the experimental method, which lacks the capacity to interpret the environment and each patient as an individual. Also the conventional classification of disease may not adequately describe the signs, symptoms and illnesses, which are likely to be presented to complementary practitioners, such as subjective symptoms eg pain. The experimental methodology does not allow the unique holistic environment of the individual to be interpreted.

iii. Uncontrollable variables

In order to control for variations in the effect of therapy, patients in experimental studies are randomised into study groups. In complementary therapies however the variations in the effect of therapy (such as patients' differential responses to the therapy) may be lost in an experimental methodology due to the need for strict control over the number of variables being measured (the variable which demonstrated an effect may be mistakenly omitted).

iv. Clinical setting as context of research

Using complementary therapies in experimental studies prevents the therapist from being able to treat the patient as he/she would usually chose, because for example only one aromatherapy oil is chosen to test for its effect. The therapist would usually use more than one oil and it would be used to treat more than one ailment. When controlling for such factors in experimental studies the holistic environment of the treatment process can be affected.

v. Practical difficulties

Some practical difficulties can arise such as, obtaining large numbers of matched subjects for treatment and control groups and it is difficult to ensure blindness when dietary, essential oils and manipulative therapies are involved. Many of the studies undertaken in massage and aromatherapy massage are pilot studies using limited sample sizes. These will probably not be used to gain further funding for a larger study but will remain as small studies producing limited results which have limited use in the evidence base for massage and aromatherapy massage.

Whilst the points raised by McGourtney and Hotchkiss (1993) are interesting they remain weak in their argument regarding the use of randomised controlled methodology to measure the effect of complementary therapies. Experimental studies which are well designed have the ability to incorporate some of the points raised by McGourtney and Hotchkiss (1993). If future work is to demonstrate that complementary therapies are effective then it is necessary to control variables to measure an effect. Collaboration of practitioners and researchers to assist in the design of future research would be useful to help ensure that common areas which are omitted (such as patient individuality) can be integrated into the research design. Collaboration would also ensure that both practitioners and researchers understood the problems associated with undertaking research in this area (control verses individuality) and could help to increase funding so that smaller studies could be used as pilot studies (to build upon in future work).

Some practitioners have suggested newer and more appropriate methods of evaluating complementary therapies (Roche et al 1987, Canter 1988, Aldridge 1989, McGourty and Hotchkiss 1993). Roche et al (1987), have suggested developing 'intra-subject' and 'inter-subject' research designs, which involve small groups and individuals in order to examine the two-way dialogue which exists between the therapist and the patient. The two-way passage of information between therapist and patient is thought to contribute to the beneficial effects of the therapy.

Aldridge (1989) undertook a study to develop appropriate research methods for use in music therapy. He concluded that there was no one paradigm for scientific research and that when considering music therapy both art and science need to be considered together. Aldridge (1989) intended to develop methodological approaches which incorporated a mutual dialogue between 'creative music therapists and anthropologists of medicine'. Although Aldridge (1989) suggested that new research methodologies should be developed, he did not make these explicit in his publication.

Many new methodologies have yet to be developed and have not been tested and this affects the reliability to test the effects of complementary therapies. The BMA (1986) and other orthodox scientists have not readily accepted new methodologies, and have preferred research to be undertaken using conventional methods to determine outcomes. It has been suggested that orthodox science undertakes only quantitative research which is objective in measurement, whereas research into complementary therapies is holistic in nature, and therefore some qualitative (mainly subjective) evaluation needs to be undertaken to measure spiritual and emotional aspects of the therapies.

It is clear that further research needs to be undertaken to understand the strengths and weaknesses of existing approaches to research into complementary therapies. The research question has changed from does it work? (experimental approaches), to what kinds of treatment produce what changes, in which patients? However in order to achieve the second approach the sample size required to demonstrate any effect would need to be large. Research into complementary therapies should concentrate on different study interactions within biological, social and psychological parameters. The present study aimed to address each of these issues. Byrne (1992), suggested that it is difficult to produce proven scientific research into complementary therapies, thus limiting and prohibiting the use of therapies in clinical practice on the grounds of academic credibility. By undertaking an experimental approach to the research, questions can be answered, and issues raised to enhance the profile of complementary therapies which can then be re-examined using different research methodologies. Also, McGourty and Hotchkiss (1993) point out that quality of life measures should be used to acknowledge the interactions of therapies with biological, social and psychological parameters. This study incorporated the SF36, quality of life scale (Ware and Sherbourne 1992) and the Hospital Anxiety and Depression scale (Zigmond and Snaith 1983) to obtain data regarding these parameters. Few studies measured quality of life except for those studies examining the effect of therapies in oncology and palliative care.

Experiential factors need to be addressed from the therapists and the patients' viewpoint, including assessing how people experience their illness and their experience of therapies. Although many of the research methods (case histories, subjective data of benefits to patients, personal testimonies and anecdotal accounts) used to gain such information have been criticised, all offer valuable research tools to evaluate therapies.

Medical research has previously focused on what the practitioner is doing rather than recognising that there is a very important role for the patient. It is important to note the significance of the relationship between the patient and the practitioner. Methods of incorporating the ideas of patients and of practitioners may also be a useful method of demonstrating the effects of complementary therapies.

However, critics still remain sceptical regarding new methodology suggesting that it is not rigorous enough to provide the much needed evidence of the effects claimed by practitioners of complementary therapies (BMA 1993). This study utilised a traditional methodology to provide some research evidence to both orthodox and non-orthodox health care workers. A recent telephone survey by Ernst and White (2000) concluded that "CAM is prevalent in the UK and therefore its scientific validation has become an ethical imperative". The Aromatherapy Organisations Council explained that randomised controlled trials are not always appropriate methods for CAM research. Kleijnen et al (1994) pointed out that the self-healing properties of CAM may be considered as a placebo response in randomised controlled trials and therefore makes the conducting of trials in aromatherapy difficult.

A paper by Fitter and Thomas (1997) suggested that although clinical trials may be difficult to undertake in CAM research there is a need to maintain randomisation in the research design. They suggested a method of randomisation, which maximises the population utilised in the analysis but maximises patient preferences and allows practitioners to give individual treatments as appropriate and develop relationships without constraints. In a further paper by Thomas and Fitter (1997a) they go on to explain the use of a pragmatic trial. They suggested that these trials might be useful in CAM research as they provide practitioners with the opportunity to offer what they consider to be the best clinical practice, individualised for each patient, which is very much the ethos of CAM in practice. It would be an interesting methodology for research in CAM to use.

However as Richardson (2000) suggested, "the randomised controlled trial remains the 'gold standard' within conventional medical research and has in some cases been applied to the evaluation of complementary therapies, it is important that this form of evidence is used, where possible, to provide substantiation of effectiveness"

The provision of an evidence based health service requires not only explanatory trials to identify the precise nature of what causes a therapeutic effect, but also pragmatic trials, which capitalise on the therapeutic intervention as a complete package, involving individualised treatments and an interaction with a health care provider. Where possible, such pragmatic trials should be randomised and/or the experimental groups assessed for equivalence in order to identify potential sources of bias.

2.4. Professional Implications for Practice

2.4.1. Training

In recent years, there has been an additional focus to the use of complementary therapies, and that is the question of professional qualifications with regards to having suitably qualified therapists to undertake the relevant therapeutic roles. This has resulted in health professionals needing to gain clarity of their ability to practice and to demonstrate with certification, the extent of their knowledge. There have been debates about this topic with different views emerging (Rankin-Box 1995). The public has been alerted to the need to visit suitably qualified therapists but many training schools exist for different therapies and regulatory bodies have only recently come into existence (for example, the Parliamentary Bill to regulate osteopathy was not passed until 15th January 1993). Trevelyan and Booth (1993) claimed that, 'training standards varied enormously across the therapies and within particular therapies, not every therapy had an enforceable regulatory mechanism in the UK. Anyone with or without training could set up as a complementary therapist'.

Prior to this time the public had little knowledge of the distinction between a 'good' practitioner trained to a specific standard, and a self-taught practitioner. Training standards and qualifications were closely scrutinised as the general public became aware of inadequacies of information regarding the training of therapists, and requested access to this information. The public want to be able to make an informed decision as to which practitioner they visit, and no longer want to decide through word of mouth. Many health care workers have chosen to undertake training in at least one complementary therapy. It has become very difficult to define competence, as there are enormous variations in training programmes, regulatory bodies and no universally agreed criteria for training (Wright 1995). The question of different forms of competence has also arisen, depending on the purpose for which the therapy is used, for example homeopathy training, takes six months full time study following qualification as a doctor, whilst for massage or aromatherapy many courses are available for which there are different entrance requirements, and different course components, resulting in dissimilar standards. Some courses have now been validated in the nursing profession by nurses' own professional bodies (the national boards), for example ENB N17 Aspects of Therapeutic Health, thus ensuring that competence and an agreed standard has been achieved, which is important for patient safety as well as indemnity in case of negligence claims.

There is a dichotomy in the amount and type of training which is required, depending which complementary therapy is being studied. Some therapies, for example osteopathy requires four years full time training, homeopathy requires registration as a doctor before being undertaken, whilst aromatherapy, reflexology and massage require courses of training to be undertaken from as little as one week up to one year. Nurses have mainly practiced in those therapies that require a shorter course of training rather than a degree course, and this has tended to be those therapies that are used as an adjunct to conventional medicine and are therapeutic and caring in nature. Due to the diverse nature of training in complementary therapies, concerns have been raised regarding the content, duration and standardisation of courses.

In 1989, the first council directive for standardising training in complementary therapies was published (European Commission 1989). This document suggested a minimum of three years training, and in some cases would involve the therapist having to acquaint themselves with the medical and legal precedents of the country in which they aim to practice. However, this method of training does not differentiate between complementary medicines such as homeopathy and acupuncture, which allow a person to diagnose and treat, and complementary therapies that have a supportive therapeutic role such as aromatherapy and reflexology, and may therefore may not require as in-depth training. Wright (1995) has stated that "there is a qualitative difference in the competence required when using complementary therapies as an aid to caring, from their use as a treatment for a particular disease".

Rankin-Box (1995), suggested that training courses could all evolve from a two year base, followed by a further year specialising in the therapy of their choice in a final year. She also suggested that the courses should take a modular approach and that nursing and medical applicants should have some accreditation for their prior knowledge.

Budd and Mills (2000) found that 'the majority of professionally qualified aromatherapists are represented by the Aromatherapy Organisations Council', and that therapists recognised by the council have been trained to a core curriculum. The council's minimum educational requirement for membership is nine months part-time, which adds up to 180 hours, plus fifty hours supervised treatment hours. Recently, The House of Lords Science and Technology Committee (2000) have recommended that the United Kingdom Central Council for Nursing, Midwifery and Health Visiting (UKCC) work with the Royal College of Nursing (RCN) to make complementary and alternative medicine a familiar part of the undergraduate nursing curriculum and a standard competency expected of qualified nurses, so they are aware of the choices their patients may make.

The need for adequate training in complementary therapies is essential, because as Price (1995) pointed out, there is no health service that can risk employing staff who are inadequately trained in the use of essential oils, especially with patients who are already in a state of ill health.

2.4.2. The Extended Role

Recent interest in the use of complementary therapies is widespread, but the documentation of its use is poor, and this to some extent may have led to restrictions in practice. Nurses have also been restricted in their practice of complementary therapies within hospital environments, by requiring doctors' permission to massage or to use aromatherapy (Booth 1993). This is unusual, because doctors remain sceptical regarding the use of complementary therapies and are often not trained in their use. Therefore this does not put them in a better position to decide whether the patient could receive complementary therapies or not. The use of complementary therapies in nursing reflects a movement towards regaining and reasserting the centrality of caring and the therapeutic aspects of nursing within a professional framework. There is a profuse and diverse bulk of literature written about complementary therapies in nursing (Jackson 1995, Turton 1989, Tattam 1992, O'Byrne 1990), however, much of the literature discusses different therapies or the impact, implications and restrictions, including accountability of using them (Rankin-Box 1991). Nurses are extending and expanding the nursing role and are clarifying the parameters of their activities and therefore must accept professional and legal accountability for their actions. There is concern that with the rapid surge of interest by nurses into complementary therapies that, principles of good training will be overlooked in the rush to provide patients with a more personal form of health care.

Salvage (1990) has suggested that the 'new nursing' role is characterised by an holistic approach, autonomy, professionalism and an active partnership between patient and nurse and a belief in the therapeutic power of nursing. The argument by

Salvage (1990) regarding the extended role of the nurse moves away from the medical model of mini doctors and encourages nurses to develop therapeutic skills such as those used in complementary therapies. This argument was endorsed by Cole and Shanley (1998) who suggested that nurses should include complementary therapies as part of their extended role. The Scope of Professional Practice (UKCC 1992) also allows nurses the freedom to move in more imaginative ways to develop new skills (not just taking over doctors work).

However, Booth (1993) suggested that nurses who are interested in complementary therapies are making a move back to 'hands on' nursing and are moving away from resource management, budgets and off duty. This role may then be seen as a mainstream-nursing role and not as an extended practice requiring additional training. Nurses are continually taking on extended practices, and they should be valued for this, not just accept it to be part of the job. To enable nurses to take on this role they need to make informed decisions regarding practice and treatment, without the need for consent to treat from the medical profession.

Rankin-Box (1993) suggested that if nursing wanted complementary therapies to exist as a mainstream nursing practice, then it requires standardisation of education and needs to be aware of the legal accountability. There is also a need to improve the research base in this area. Rankin-Box (1992) stated that "therapists claiming to treat or cure certain ailments on the basis of anecdotal evidence as opposed to definitive research evidence may leave themselves open to ethical, legal and professional concerns". Nurses need a well-defined research base upon which to justify their actions and this is necessary to allow nurses to expand/extend their role. "The specific knowledge demanded from these therapeutic interventions argues the case for formally recognised and standardised training courses to be established in parallel with for example orthopaedic or oncology specialities". Therapies used within a well-established profession, such as nursing, have a responsibility to uphold the code of professional conduct and ensure high standards of professionalism. It is important that training through appropriate bodies is undertaken, as nursing must adhere to the UKCC Code of Professional Conduct (1984). Rankin-Box (1994) suggested that specialised training courses in parallel with orthopaedic/oncology nurse training are required to gain status in the use of complementary therapies in nursing.

In 1995, Bay suggested that nurses might find that the use of complementary therapies in practice may become a task rather than part of an extended role. She suggested that if nurses do not strive to develop a service to their requirements then nurses might be left on the sideline organising other people to provide this therapeutic service. With doubts regarding the efficacy of many therapies it is difficult to convince purchasers of services about the value of complementary therapies.

Recently, Cole and Shanley (1998) has debated the controversy surrounding the development of the extended role for nurses focusing on the introduction of complementary therapies, and suggested that these should be legitimate components of the new nurses role.

It is essential that training through appropriate bodies be undertaken. Nurses must consider, legal accountability, patient advocacy, professional competency, the extended role of the nurse and the diagnostic aspects of some therapies used in conjunction with orthodox medicine. Armstrong (1985) also recognised the need for the standardisation of quality in training and curricula, codes of conduct, principles of ethical practice and a disciplinary board to enforce this. Some therapies already require registration to practice such as osteopaths, homeopaths and chiropractics.

2.4.3. Guidelines for Practice

Guidelines for the use of complementary therapies in clinical practice began to be developed in the late 1980s. In 1989 a policy document was developed in Bath Health Authority for using complementary therapies as an adjunct to orthodox treatments. Strict guidelines were developed in which therapists (including trained nurses) could practice, and this has enabled nurses in this health authority to incorporate complementary therapies into their practice to enhance care.

In 1992 the UKCC guidelines regarding the administration of medicines were introduced (UKCC 1992, 'Standards for the administration of medicine', paragraphs 38 and 39). They make explicit that the practice of using complementary therapies on patients must only be carried out by nurses who have successfully undertaken training in complementary therapies, and that nurses must remain accountable for their practice.

The UKCC (1992) again refer to the safe practice of complementary therapies in their document 'The scope of professional practice' (paragraphs 8 to 11), "It is the responsibility of the individual practitioner to judge whether a qualification obtained on complementary therapy has brought the practitioner to an appropriate level of competence to use that skill in patient or client care".

The European Commission (1990), also have shifted the onus of responsibility for disproving malpractice from the patient or client onto the practitioner. It will be up to the individual practitioner to provide sound evidence to justify treatment should a patient formally claim they were disadvantaged in some way as a result of therapy.

Wafer (1994) has implemented the use of complementary therapies into nursing practice in the nursing development unit in Tameside, addressing the issues of storage of oils and the method of delivery as well as a selected number of oils to be used. A list of guidelines were developed for the use of massage and aromatherapy in nursing practice

In 1994 the RCN established a complementary therapies in nursing special interest group. They developed a statement of beliefs regarding the use of complementary therapies by nurses and gave advice regarding their safe use. It is important that anyone who is practising any form of complementary therapy is aware of local policies that may exist, and to be sure of their insurance cover from their professional organisation or trade union.

These recent developments in health care regarding the use of complementary medicine will heighten knowledge and will safeguard patients by the introduction of guidelines and codes of conduct for each health authority. Due to the increased emphasis on accountability, there may be a realisation that more empirical research studies need to be undertaken to ensure that practices which are being carried out are of therapeutic value.

If nurses want to utilise CAM in nursing practice they should be aware of evidence for the effectiveness of the therapy. Whilst there has been limited research into CAM therapies, especially those which nurses utilise, then the possibility of incorporating therapies into practice will be limited by financial constraints. Purchasers of services will be hampered by lack of credible evidence for effectiveness.

These recent developments in health care regarding the use of complementary medicine will heighten knowledge and will safeguard patients by the introduction of guidelines and codes of conduct for each health authority. Due to the increased emphasis on accountability, there may be a realisation that more empirical research studies need to be undertaken to ensure that practices which are being undertaken are of therapeutic value. Nurses need to be aware of the research issues and how to judge the quality of research evidence in complementary therapy, in order that they can provide appropriate advice to patients, and move toward integrating effective therapies into their practice.

2.5. Massage

The following section has explored the history of massage and related literature, and has presented an in-depth review of the limited research. The section has focused on massage only and does not include studies that used massage and aromatherapy together. The literature was divided into anecdotal literature (table 2.8) and empirical literature (table 2.9) and was presented by grouping studies of similar specialities, for example, normal female populations, acute care, oncology, the elderly, paediatrics and others (tables 2.10-2.15). The literature was also reviewed using outcome measures utilised in the studies. They incorporated both physiological measures (table 2.16) and psychological measures (table 2.17).

2.5.1. Historical Perspectives

Massage is an ancient art that dates back many thousands of years. It is thought to be the oldest of complementary therapies and was linked with the most sought after of all human needs; touch (Le Boyer 1976). Massage was thought to have been used by the Chinese as far back as 3000 years BC, and there are references in text in India written in 1800 BC. The use of massage spread through Greece and Rome where in the second century AD, Galen was recommending massage to the gladiators before and after exercise. Massage was thought to decrease in popularity in the Middle Ages, but by the 16th century physicians in France were keen exponents of the art. Per Hendrick Ling a Swedish doctor in the 19th century developed a scientific system of massage, now known as Swedish massage that became popular with the medical profession. As technology improved there was a move away from massage as a therapy until the recent boom today where massage is being incorporated into many areas of health care.

There are two main types of massage, Swedish massage and therapeutic massage. Swedish massage incorporates stronger and firmer movements into its procedure whilst therapeutic massage tends to be relaxing and calming with gentler movements (Turton 1989). Swedish massage or general massage techniques involve a variety of movements starting with gentle stroking, gradually progressing to stronger movements such as rubbing or kneading. Farrow (1990), suggested that "massage is the systematic manipulation of the soft tissues to help promote comfort and healing", whereas therapeutic massage is defined as "a rhythmic, sensitive form of touch, performed by a specially trained individual with a desire to communicate empathy to the recipient, thus producing positive psychological and physiological states of being" (Wright 1987). Some of the studies (Groer et al 1994, Corley et al 1995) described the type of massage used, as a 'back rub'. These studies were included if the back rub was for relaxation purposes and involved therapeutic massage procedures such as effleurage, or if similar outcome measures were used.

Along with other complementary therapies, the use of massage in health care has undergone a renewal of interest with numerous disciplines using this ancient art integrated in their practice (Holmes 1986, Turton 1989, Passant 1990, Emly 1993). However, although massage appears to be popular in health care at the present time, there is limited literature to substantiate its use and this is evidenced by the review. Forty-four papers were retrieved regarding the use of massage in clinical practice. Twenty of these papers were anecdotal in nature (45%) and twenty-four (55%) were empirical studies. There has been an increase in the proportion of empirical literature published in the last ten years.

2.5.2. Anecdotal Massage Literature

A review of the anecdotal literature elicited 20 articles, table 2.8. These articles were reviewed by dividing them into groups relating to the topics they described ie acute care, oncology, paediatrics, disabilities and GP practice.

Table 2.8 Summary of Anecdotal Literature relating to the use of Massage, presented chronologically.

Author	Speciality
Michelsen (1978)	How to massage
Joachim (1983)	How to massage
Taylor (1983)	How to massage
Ashton (1984)	Acute care
Holmes (1984)	Acute care
Chabrier (1987)	How to massage
Byass (1988)	Oncology
Turton (1989)	Oncology
Passant (1990)	Oncology
Paterson (1990)	Paediatrics
Smith (1990)	Acute care and oncology
Fromant (1991)	Acute care
Carruthers (1992)	Acute care
Pietroni (1992)	General Practice
Emly (1993)	Disabilities
Hill (1993)	LITERATURE REVIEW
Trevelyan (1993)	How to massage
Kirshbaum (1995)	Oncology
Watson (1997)	Effects of massage
Kimber (1998)	Acute care

The earliest literature explained how to perform massage (Michelsen 1978), with literature in the 1980's also describing the best method to use, to give a 'good' massage (Joachim 1983, Taylor 1983, Chabrier 1987). Another article (Trevelyan 1993) also described the massage technique, and substantiated some of her claims by reviewing some relevant research (Scafidi et al 1990, Fraser and Kerr 1993, Byass

1988 and Pietroni 1991). Recently Watson (1997) presented a review of the benefits of massage.

The literature review produced six papers of anecdotal information relating to the use of massage in acute care (Ashton 1984, Holmes 1986, Smith 1990, Fromant 1991, Carruthers 1992 and Kimber 1998). Ashton (1984), Holmes (1986) and Smith (1990), all claimed that massage was beneficial for cardiac patients by helping to reduce stress and make patients feel more relaxed. Fromant (1991) and Carruthers (1992) both suggested that the used of massage in intensive care could help to relieve tension, alleviate anxiety and reduce stress. In 1993, Hill undertook a limited literature review of some of the available evidence regarding the benefits of massage for patients in intensive care. Kimber (1998) found that massage in pregnant women over 36 weeks gestation was useful for helping them to cope with pain and gave them positive feelings about labour.

All of these papers have been useful in highlighting areas within acute care where massage may be beneficial such as stressful situations within coronary care, intensive care and midwifery. This literature suggested that patients may find massage relaxing and may therefore require less analgesia during painful procedures.

Five papers were found relating to oncology and/or care of the dying patient (Byass 1988, Turton 1989, Smith 1990, Passant 1990, Kirshbaum 1996). These studies describe the benefits of massage to both the masseur and the patient when caring for terminally ill patients and suggested that they would both feel psychologically rewarded by feeling good about themselves. It is advocated that everyone concerned with caring for dying patients should learn the techniques of massage so that a 'beneficial, holistic and harmless means of helping patients live until they die, could be given (ie a massage). These studies suggested that massage helped to ease the physical discomfort associated with dying and reduced feelings of isolation and fear that patients suffer when they are nearing death. Massage is an important form of communication for use with dying patients. Some of this literature gives evidence of patients' enjoyment of massage by including positive comments concerning their feelings. These papers again identify some areas which would be useful to investigate further regarding the used of massage when caring for dying patients, which would include the therapeutic relationship between the masseur and the patient, reduction in the physical symptoms, anxiety and feeling of isolation associated with dying.

In the early 1990's literature was produced in diverse areas of nursing including, neonatal nursing (Paterson 1990), nursing disabled patients (Emly 1993) and GP practice (Pietroni 1991) which suggested beneficial effects of massage including improving mother baby relationship and easing constipation.

Although many of the papers have suggested beneficial effects of massage, including relaxation, reduction in stress, reduction in pain and less feelings of isolation, there are no case studies using large enough sample sizes or reliable and valid methodology that have produced substantial evidence demonstrating these effects. The papers refer to different clinical situations, identify different patients and do not use similar massage techniques to provide any rational for the use of massage in any of the areas discussed. However many of the papers describe the benefits that patients express, such as feeling better, more comfortable and restful. Patients comment on how they enjoyed the massage. These variables are difficult to measure in research studies, and currently anecdotal literature is the only format where subjective feelings are reviewed as evidence of effectiveness. Further empirical work needs to be undertaken building upon the foundations recognised within the anecdotal literature.

It is interesting to note that all the anecdotal literature presented is by a single author. One suggestion for this is that there are probably many therapists working in isolation to demonstrate effects of therapies, many of who will probably have poor research skills. Practitioners of complementary therapies need to collaborate with specialists in research and the clinical area to enable good quality collaborative research to be undertaken.

2.5.3. Empirical Massage Literature

Although there is relatively little empirical evidence to substantiate the use of massage in clinical practice there is a developing body of research literature, which has begun to provide evidence of the value of massage. A total of 24 studies were extrapolated from the literature, table 2.9.

These studies were comprehensively reviewed in tables by grouping them into their relevant clinical speciality; normal female populations (table 2.10), acute care (table 2.11), oncology (table 2.12), care of the elderly (table 2.13), paediatric care (table 2.14) and others (table 2.15).

Table 2.9 Summary of Empirical Research relating to the use of Massage, presented chronologically.

Author	Clinical Speciality
Barr and Taslitz (1970)	Students
Longworth (1982)	Staff
Sims (1986)	Oncology
Bauer and Dracup (1987)	Acute
Fakouri and Jones (1987)	Elderly
Field et al (1987)	Paediatrics
White-Traut and Goldman (1988)	Paediatrics
Farrow (1990)	Acute
Tyler et al (1990)	Acute
Weinrich and Weinrich (1990)	Oncology
Scafidi et al (1990)	Paediatrics
Field et al (1992)	Depressed adolescents
Ferrell-Torry and Glick (1993)	Oncology
Meek (1993)	Oncology
Fraser and Ross Kerr (1993)	Elderly
Groer et al (1994)	Elderly
Corley et al (1995)	Elderly
Sunshine et al (1996)	Fibromyalgia
Field et al (1997)	Chronic fatigue syndrome
Field et al (1998)	Acute
Ersser et al (1998)	Elderly
Richards (1998)	Acute
Hulme et al (1999)	Acute
Hayes and Cox (2000)	Acute

Table 2.10 Massage Studies in Normal Female Populations

Author	Design	Sample	Methods	Number of interventions	Massage	Measures	Time measures taken	Findings
Barr and Taslitz (1970)	Quasi-experimental Patients acted as own controls	N = 10 Female undergraduate college students (aged 19-21)	All subjects received 3 control periods of 20 minutes and 3 massage interventions of **20 minutes** Both were followed by 20 minutes rest over a six day period	3	Back massage by qualified physical therapist following a set time and protocol lasting 20 minutes followed by 20 minutes rest All massages or control periods were conducted at the same time of day. The massage and control period were alternated on a daily basis commencing with a control period.	**Physiological**; HR, BP, RR, galvanic skin response, skin temperature	Pre, during and post	Preliminary findings not significant but suggest that massage has a stimulating effect in sympathetic activity
Longworth (1982)	Exploratory	N = 32 Female staff and students at a school of nursing who were normotensive (aged 19-52)	All subjects received the same set procedure in the same order, once; 10 minute baseline, **3 minute** massage, **6 minute** massage and 10 minute rest	1	Slow stroke back massage by the investigator to ensure consistency of technique lasting 3 minutes followed by a second massage lasting 6 minutes	**Physiological**; HR, SBP, DBP **Psychological**; STAI	HR, SBP, DBP measured every minute, pre, during and post STAI measured pre and post	No significant changes in physiological variables Significant decrease in STAI scores following massage ($p<0.0001$)

Key
HR – heart rate
BP – blood pressure SBP – systolic blood pressure DBP – diastolic blood pressure
RR – respiratory rate
STAI – State-Trait Anxiety Inventory (Spielberger et al 1983)

Table 2.11 Massage Studies in Acute Care

Author	Design	Sample	Patients Ventilated	Methods	Number of interventions	Type of massage	Measures	Time measures taken	Findings
Bauer & Dracup (1987)	Quasi-exp. 1 group	N = 25 Cardiac patients	No	**6 minute** back massage Patients acted as own controls	1	Standardised, undertaken by one nurse, independently	**Physiological;** HR, SBP, DBP, electromyogram, skin conductance, skin temperature	10 mins pre massage Immediately pre massage Immediately post massage 10 mins post massage	No significant findings, minor changes in all variables All patients found massage favourable but one
Tyler et al (1990)	Quasi-exp. 1 group	N = 173 Critically ill patients	Yes	**1 minute** back rub Patients acted as own controls	1	Standardised, undertaken by the investigator	**Physiological**; HR, mixed venous oxygen	Immediately post massage 1, 2, 3 & 4 mins post massage	Significant decrease in O2 saturation (p=0.0001) and increase in heart rate in 1st minute of back rub (p=0.0001) No clinical significance but 1st minute may cause patient to become unstable
Farrow (1990)	Case studies	N = 30 Acute surgical adults	No	Massages to any part of the body lasting **any length of time**	1 or more (dependent on length of stay)	Not standardised, undertaken by 2 investigators	**Psychological;** Written notes of patients reactions and comments during and after the massage	During massage Post massage for six weeks	Only five cases reported upon, mainly positive patient comments. No objective measures used. NB.25 patients unaccounted for.
Field et al (1998)	RCT 2 groups	N = 28 Adults with burn injuries	No	Grp1, n=14; **20 minute** massage to the back, face, chest, stomach and arms Grp2, n=14; sit and relax for 20 minutes (C)	7 (once a day for 1 week)	Standardised, undertaken by independent massage therapist	**Physiological**; HR, cortisol levels, pain **Psychological**; STAI, behaviour observation, POMS	Immediately pre intervention Immediately post intervention	Significant decrease in heart rate (p=0.005), pain (p=0.01), anxiety (p=0.01) in those who received massage Significant improvement in POMS score for depression (p=0.01) and anger (p=0.05)

Key overleaf

Table 2.11 Massage Studies in Acute Care, continued.

Author	Design	Sample	Patients Ventilated	Methods	Number of massages	Type of massage	Measures	Time measures taken	Findings
Richards (1998)	RCT 3 groups	N = 69 Critically ill male patients	Yes	Grp1, n=24; **5 minute** back massage, once Grp2, n=28; 7.5 minute relaxation, once Grp3, n= 17; usual care (C)	1	Standardised	**Physiological**; sleep using EEG, **Psychological**; sleep using patients reports	Post massage	No significant difference between the 3 groups Quality of sleep improved for patients in the back massage group compared to patients in the control by one hour
Hulme et al (1999)	RCT 2 groups	N = 59 Post operative female patients	No	Grp1, n=30; **5 minute** foot massage and analgesia Grp2,n=29; analgesia only (C)	1	Not standardised, undertaken by investigator	**Physiological**: Numerical pain intensity scale **Psychological**; Questionnaire to examine satisfaction, memory and analgesia taken	On the day following surgery	Patients in experimental group had significantly less pain over time than the control group ($p = 0.038$)
Hayes and Cox (2000)	Quasi-exp. repeated measures 1 group	N = 25 Critically ill patients	Yes (n=13)	**5 minute** foot massage Patients acted as own controls	1 –10 Mean 2.7 per patient (range 1-10)	Standardised, undertaken by independent research assistant	**Physiological**; HR, MABP, RR, SO2	Mean of 5 mins pre massage, 5 mins during massage and 5 mins post massage	Significant decrease in HR, $p<0.02$ RR , $p<0.001$ and MABP $p<0.001$, following the foot massage intervention

Key
RCT- randomised controlled trial
HR – heart rate
MABP – mean arterial blood pressure
POMS – Profile of Mood States (McNair et al 1971)
C- control
SBP – systolic blood pressure
SO2 – oxygen saturation
Min – minute
DBP – diastolic blood pressure
RR – respiratory rate
STAI – State Trait Anxiety Inventory (Spielberger et al 1983)

Table 2.12 Massage Studies in Oncology

Author	Design	Sample	Methods	Number of interventions	Type of massage	Measures	Time measures taken	Findings
Sims (1986)	PILOT Quasi-experimental design 2 groups	N = 6 Females with breast cancer receiving radiotherapy	Grp1, n=3; 3 daily, **10 minute** back massages, followed by 3 rest days Grp2, n=3; 3 rest days followed by 3 daily, 10 minute back massages	3	Slow stroke back massage carried out by trained researcher at any time point Standardised by time only (not movements)	**Psychological;** Mood using a likert scale Symptom distress using SDS Patient comments	SDS – pre and post total massages and total rest Mood – pre and post every massage and post total rest	No significant findings 25% improvement in symptom distress and 17.9% improvement in overall mood in experimental group compared to 7.7% and 13.8% respective improvement in the control group All comments were positive
Weinrich and Weinrich (1990)	PILOT RCT 2 groups	N = 28 Patients with cancer	Grp1, n=14; one **10 minute** back and neck massage Grp2, n=14; one 10 minute visit	1	Swedish back massage carried out by trained data collector at a set time point Standardised - unknown	**Physiological;** Pain using VAS	Immediately pre and post, 1 hour post and 2 hours post intervention	Significant decrease in pain levels immediately after the massage in male patients, $p=0.01$
Ferrell-Torry and Glick (1993)	Exploratory 1 group	N = 9 Males with cancer	Massaged for **30 minutes** on feet, back, neck and shoulders on two consecutive evenings. Patients acted as own controls	2	Therapeutic massage carried out by investigator at a set time point	**Physiological;** HR, RR, BP Pain using a VAS **Psychological;** Anxiety using STAI	Immediately pre, post and 10 mins post intervention	Massage significantly reduced pain levels by 60% (day one, $p=0.007$ and day two, $p=0.025$) and anxiety levels (day one, $p=0.02$ and day two, $p=0.004$) 58% (n=5) said they felt more relaxed HR,RR and BP all showed a decrease
Meek (1993)	Quasi-experimental repeated measures 1 group	N = 30 Adults with terminal stage illness in an hospice	Slow stroke back massage for **3 minutes** on two consecutive days	2	Slow stroke back massage carried out by investigator at approx same time point Standardised by time and movements	**Physiological;** SBP, DBP, HR, skin temperature	Pre, post and 24 hours post intervention	Significant decrease in HR ($p<0.002$), SBP ($p<0.000$), DBP ($p<0.000$) and skin temperature ($p<0.000$)

Key
RCT – randomised controlled trial HR – heart rate RR – respiratory rate
BP – blood pressure SBP – systolic blood pressure DBP – diastolic blood pressure
STAI – State Trait Anxiety Inventory (Spielberger et al 1983) VAS – visual analogue scale (McGuire 1988) SDS – symptom distress scale (McCorkle 1981)

Table 2.13 Massage Studies in the Elderly

Author	Design	Sample	Methods	Number of interventions	Type of massage	Measures	Time measures taken	Findings
Fakouri and Jones (1987)	Quasi-experimental 1 group	N = 18 Elderly patients who acted as their own controls Mean age =74	Slow stroke back rub for **3 minutes** once every evening for 3 consecutive evenings	3	Slow stroke back rub, undertaken by 2 investigators. Standardised by time and movements	**Physiological**; HR, SBP, DBP, skin temperature	Pre and post back rub	Day one and two demonstrated significant reduction ($p<0.01$) in HR (from 80 to 79 bpm) and SBP (from 132 to 121 mmhg) DBP had significantly decreased ($p<0.05$) by day three (from 71 to 66 mmhg)
Fraser and Ross Kerr (1993)	RCT 3 groups	N = 21 Long term residential elderly	Grp1, back massage for **5 minutes** Grp2, conversation for 5 minutes Grp3, no intervention All over 4 consecutive evenings Group sizes not indicated	4	Slow back massage Not explicit who undertook massage or if it was standardised	**Physiological**; HR, SBP, DBP, electromyogram **Psychological;** Anxiety using STAI	Pre and post back massage	Statistically significant reduction between the back massage group and the no intervention group ($p = 0.007$) in mean anxiety scores All reported enjoying the massage and found it relaxing
Groer et al (1994)	RCT 2 groups	N = 32 Healthy elderly	Grp1,n=14; no intervention (control) Grp2,n=18; one **10 minute** back rub	1	Slow stroke back rub, undertaken by a massager. Standardised by time and movements	**Psychological;** anxiety using STAI	Immediately pre and post back rub	No significant findings No differences between the groups in anxiety

Key overleaf

Table 2.13 Massage Studies in the Elderly, continued.

Author	Design	Sample	Methods	Number of interventions	Type of massage	Measures	Times measures taken	Findings
Corley et al (1995)	RCT 2 groups	N = 19 Elderly in a nursing home	Grp1,n=7;3 minutes of undisturbed rest (control) Grp2,n=12; one **3 minute** back rub	1	Back rub undertaken by same investigator at a set time point. Not standardised procedure	**Physiological;** HR, SBP, DBP,RR, EMG, skin temperature **Psychological;** Tactual sensitivity using a tactual minimising scale, mood using a likert scale	Pre and post back rub	No significant changes in physiological variables Women had greater tactile sensitivity than men in both groups Mood improved in both groups After a back rub 83% said they were comfortable, 67% said they felt pleased and calm and 58% were relaxed
Ersser et al (1998)	PILOT RCT 2 groups	N = 32 Elderly	Grp1,n=16; back massage for **10 minutes** Grp2,n=16; conversation for 10 minutes Both for 3 consecutive evenings	3	Slow stroke back massage undertaken by 26 trained nurse masseurs at no set time point. Standardised by time and movements	**Physiological**; sleep pattern using SPAT, **Psychological;** sleep quantity using SEST, interview	Day 1&2 - baseline data Day 1-7 – 24hr continuous sleep assessment	No significant findings Some patients found the back massage comforting and relaxing (n=?)

Key
RCT – randomised controlled trial
HR – heart rate SBP – systolic blood pressure DBP – diastolic blood pressure
bpm – beats per minute
STAI – State Trait Anxiety Inventory (Spielberger et al 1983)
SPAT – sleep pattern assessment tool (Ersser et al 1998)
SEST – subjective evaluation of sleep tool (Ersser et al 1998)

Table 2.14 Massage Studies in Paediatrics

Author	Design	Sample	Methods	Number of interventions	Type of massage	Measures	Time measures taken	Findings
Field et al (1987)	RCT 2 groups	N = 40 Pre-term neonates	Grp1,n=20; three, **15 minute** massages over three consecutive hours for 10 days Grp2,n-=20; routine care	30	Massage carried out by unknown using a set protocol of time and movements	Weight, number of feeds and formula intake and behaviour using BNBAS	Post study and 6 months post study	Neonates who received massage gained 47% more weight per day and performed better on the BNBAS than those not massaged
White-Traut and Goldman (1988)	PILOT RCT 2 groups	N = 33 Premature neonates	Grp1, n=17; massage for **10 minutes** once a day for 10 days or until discharge Grp2, n=16; routine care	10 or less	RISS used for massage undertaken by nurses at a set time	**Physiological**; HR, RR, body temperature	Pre, during and post intervention	HR and RR significantly increased, (HR = $p<0.001$ and RR = $p<0.003$) in those receiving massage Massage should be used on selected infants
Scafidi et al (1990)	RCT 2 groups	N = 40 Neonates	Grp1,n=20;Three, **15 minute** massages over three consecutive hours for 10 days Grp2,n=20; routine care	30	Massage carried out by unknown using a set protocol of time and movements	Sleep/wake behaviour Behaviour using BNBAS Weight Intensive care duration	Post study and 6 months post study	Neonates who received massage gained 21% more weight per day and performed better on the BNBAS than those not massaged

Key overleaf

Table 2.14 Massage Studies in Paediatrics, continued

Author	Design	Sample	Methods	Number of Interventions	Type of massage	Measures	Time measures taken	Findings
Field et al (1992)	RCT 2 groups	N = 72 Hospitalised depressed adolescents	Grp1, n=20; daily viewing of a relaxing videotape for 30 minutes for 5 days Grp2,n=52; daily **30 minute** back massage for 5 days	5	Relaxing massage by trained students at a set time using a set protocol of movements and times	**Physiological**; HR, levels of cortisol, adremaline, noradrenaline and dopamine in saliva and urine **Psychological**; SASC, POMS, adolescent and nurse reports of anxiety and depression	Day 1 & 5 - pre, post and 30 minutes post intervention	HR decreased significantly in children who received back massage (p=0.001) Children in the experimental group were found to be less depressed and anxious than the control group Nurses reported that night time sleeping improved among the massage group

Key
RCT – randomised controlled trial
HR – heart rate
RR – respiratory rate
BNBAS – Brazelton Neonatal Behaviour Assessment Scale (Brazelton 1983)
SASC – State Trait Anxiety Inventory for Children (Spielberger et al 1970)
POMS – Profile of Mood States (McNair et al 1971)
RISS – Rice Infant Sensorimotor Stimulation (Rice 1977)

Table 2.15 Other Massage Studies

Author	Design	Sample	Methods	Number of interventions	Type of massage	Measures	Time measures taken	Findings
Sunshine et al (1996)	RCT 3 groups	N = 30 female adults with fibromyalgia	Grp1, n=10; 30 **minute** massage Grp2, n=10; 30 minute TENS Grp3, n=10; 30 minute Sham-TENS All interventions were twice a week for 5 weeks	10	Swedish massage Unknown who undertook the massage and if a set protocol was used	**Psychological;**STAI POMS	Pre and post on day 1 and day 5 of the study	Patients who received massage had significantly lower anxiety and depression scores on the first and last days compared to their pre intervention scores (5%) and reported fewer symptoms of pain stiffness fatigue and difficulty in sleeping No significant differences between the three groups
Field et al (1997)	RCT 2 groups	N = 20 subjects with chronic fatigue syndrome	Grp1, n=10; **30 minute** massage, twice a week for 5 weeks Grp2, n=10; attention (roller probes rolled back and forth across the body for 30 minutes, twice a week for 5 weeks	10	Gentle massage given by trained massage therapist at no set time using a set protocol of movements and times	**Physiological;** pain **Psychological;**STAI POMS	Immediately post	Immediately following the massage all scores were significantly reduced ($p<0.05$) compared to the control group which continued over the 5 week period

Key
RCT – randomised controlled trial
STAI – State Trait Anxiety Inventory (Spielberger et al 1983)
POMS – Profile of Mood States (McNair et al 1971)
TENS – Transcutaneous electrical stimulation
Sham-TENS – transcutaneous electrical stimulation with no current

The tables concisely show that the use of massage has been utilised in many different areas of healthcare, using different populations and different research methodology. The majority of studies 88% (n=21) utilised experimental methodology, 67% (n=14) used strict randomised controlled trial methodology and 38% (n=8) used quasi-experimental approaches. Other methods including exploratory work and case studies have enabled the investigation and reporting of qualitative areas of interest. Even though the majority of studies utilised experimental methodology many of these studies have used a poor study structure, resulting in small sample sizes and consequently a reduction in the ability to quantify the findings. Most group sizes were approximately 30 patients due to studies using up to three groups to compare outcomes.

Reviewing the studies in tabular form enabled common areas between studies to be highlighted. The number of massage interventions varied greatly, from one massage to thirty massages and this has affected the interpretation of the results and reduced the ability to compare studies. Some results have suggested that the greater the number of massages received the greater the effect and because some studies have only utilised one massage this is difficult to quantify. It is important to determine the effects of many consecutive massages as the effect may be enhanced as the patient becomes accustomed to the procedure and the masseur. Field et al (1998) was the only study to use consecutive massages in this group of studies. The results shown in this study would have no clinical significance due to the changes in the physiological variables being minute and therefore changes in relaxation may not have arisen as suggested by the authors. However they found that by increasing the number of consecutive massages led to a decrease in anxiety and a significant improvement in depression.

It is also interesting that many studies used a variety of different people to undertake the massages ranging from the investigator to trained masseurs, and this would affect the quality of the massage. Some studies make explicit that the masseurs were trained. Some studies have used an independent masseur whilst others studies have used the investigator to undertake the massages. This can lead to bias. The studies also used different massage techniques. Five studies used a standardised procedure to ensure the massage procedure was consistent, although none of the studies undertook any reliability testing to confirm this. The length of the massage also varied from one minute to any length of time. It would be useful to determine a therapeutic time. The area being massaged also varied between the studies and this was dependent on which areas of the patients' body were accessible. Although it is useful to record the length of time and the procedure used, it may be necessary to use a less rigid technique in order to demonstrate the desired effect by tailoring the massage to the subject. However in order to compare effects and demonstrate an outcome it is important to enforce rigidity into randomised controlled trials. Patient choice was not considered in the studies. All of the studies have utilised a different massage technique, area to massage and number of massages and this would make a meta-analysis difficult.

The time the outcome measures were taken pre or post massage requires consideration. If the optimum time for recording the effect of the massage is not used then the effects of the therapy will not be measured. It is unknown when massage has the optimum effect and how long the effects last. Studies have shown effects at different time points ranging from immediately post massage to 24 hours post massage. Some studies measured effects up to six months post massage (Field et al 1987, Scafidi et al 1990).

The studies already undertaken have mainly examined the use of massage as an aid to relaxation. After reviewing the studies, two main types of massage emerged, relaxing massage and stimulating massage. However the definition and actual movements utilised was not made explicit in all studies. The studies undertaken in paediatric care used massage to induce a stimulating effect rather than a relaxing effect and these studies should only be examined in relation to paediatric care. No empirical evidence was found relating to the relaxing effects of massage within neonatal care, but the studies were able to demonstrate physiological changes in response to massage.

Other studies used a relaxing massage and many different outcome measures were utilised. The studies have demonstrated that both physiological effects (table 2.16) and psychological effects (table 2.17) of massage can be measured.

It was interesting to note that two studies using normal populations (Barr and Talitz 1970, Longworth 1982) were able to demonstrate the ability to measure some of the effects of massage and these should both be considered when compiling new research studies. However no significant physiological changes were demonstrated in either study in response to massage.

Table 2.16 Physiological Outcome Measures used in Massage Studies

Measure	Studies	Results
Heart Rate	Barr and Talitz (1970), Longworth (1982), Bauer and Dracup (1987), Fakouri and Jones (1987), White-Traut and Goldman (1988), Tyler et al (1990), Field et al (1992), Ferrell-Torry and Glick (1993), Fraser and Ross Kerr (1993), Meek (1993), Corley et al (1995) Field et al (1998) Hayes and Cox (2000)	Five studies demonstrated significant reductions in heart rate; Fakouri and Jones (1987) - p<0.01, Field et al (1992) – p<0.001, Meek (1993) – p<0.002, Field et al (1998) - p=0.005, Hayes and Cox (2000) – p<0.02 The two studies that demonstrated an increase in heart rate were in a one minute back rub and in neonatal babies. In both these studies it was expected that the heart rate would increase. All other studies demonstrated no change in heart rate in those patients who received a massage compared to those who did not.
Blood Pressure	Barr and Talitz (1970), Longworth (1982), Bauer and Dracup (1987), Fakouri and Jones (1987), White-Traut and Goldman 1988, Ferrell-Torry and Glick (1993), Fraser and Ross Kerr (1993), Meek (1993), Corley et al (1995), Hayes and Cox (2000)	Three of the studies demonstrated a significant reduction in blood pressure in those patients receiving a massage; Fakouri and Jones (1987), - p<0.01, Meek (1993) – p<0.000, Hayes and Cox (2000) – P<0.001
Respiratory Rate	White-Traut and Goldman (1988), Ferrell-Torry and Glick (1993), Corley et al (1995), Hayes and Cox (2000)	Two studies demonstrated a significant decrease in respiratory rate, Ferrell-Torry and Glick (1993), p<0.05 and Hayes and Cox (2000), p<0.001. White-Traut and Goldman (1988) demonstrated a significant increase in respiratory rate in pre-term babies (p<0.003).
Skin Temperature	Barr and Talitz (1970), Longworth (1982), Bauer and Dracup (1987), Fakouri and Jones (1987), White Traut and Goldman (1988), Meek (1993)	One study demonstrated a significant increase in skin temperature (Fakouri and Jones (1987) p=0.01) All studies showed that temperature rose during the first part of the massage and then fell.
Electro-myography	Longworth (1982), Bauer and Dracup (1987), Fraser and Ross Kerr (1993), Corley et al (1995), Richards (1998)	All studies showed a decrease in electromyogram activity but not at significant levels
Oxygen Saturation	Tyler et al (1990), Hayes and Cox (2000)	Tyler at al (1990) demonstrated a a significant (p=0.0001) decrease in mixed venous oxygen whilst the study by Hayes and Cox (2000) showed no changes
Pain	Ferrell-Torry and Glick (1993) used a VAS scale Weinrich and Weinrich (1990), Field et al (1997) and Field et al (1998) used the Short Form McGIl pain questionnaire Hulme et al (1999) used a numerical pain intensity scale	All studies showed significant reductions in reported pain in those patients who received a massage. The study by Weinrich and Weinrich (1990) only demonstrated significance in male patients

Table 2.16 Physiological Outcome Measures used in Massage Studies, Continued

Galvanic skin response	Barr and Talitz (1970), Longworth (1982), Bauer and Dracup (1987)	Longworth (1982) found a significant increase before and after the massage
Cortisol levels	Field et al (1997), Field et al (1998)	Both studies demonstrated significant reductions ($p<0.05$)

Table 2.17 Psychological Outcome measures used in Massage Studies

Measure	Studies	Results
Spontaneous Comments	Longworth (1982), Sims (1986), Bauer and Dracup (1987), Fakouri and Jones (1987), Farrow (1990), Field et al (1992), Fraser and Ross Kerr (1993), Corley et al (1995), Richards (1998)	All comments were positive. Patients expressed enjoyment of the massage experience.
Spielberger State-Trait Anxiety Inventory (STAI)	Longworth (1982), Field et al (1992), Ferrell-Torry and Glick (1993), Fraser and Ross Kerr (1993), Groer et al (1994), Sunshine et al (1996), Field et al (1997), Field et al (1998)	Field et al (1992), Sunshine et al (1996) and Field et al (1998) showed a significant reduction in anxiety in those who received a massage ($p<0.05$)
Symptom Distress Scale (SDS)	Sims (1986)	Those who received a massage showed an improvement in symptom distress measures but not at a significant level
Mood – using likert scale or Profile of Mood State (POMS, McNair et al 1971)	Sims (1986) and Corley et al (1995) used a likert scale Field et al (1992), Sunshine et al (1996), Field et al (1997) and Field et al (1998) used POMS	All studies demonstrated an improvement in mood and depression in those who received the massage
Relaxation – using VAS	Ferrell-Torry and Glick (1993)	Demonstrated significant improvement in relaxation following the massage ($p<0.005$)

Although the studies have demonstrated that the effects of massage can be measured, not all studies showed an effect or gave similar results. Various different outcome measures have been recorded at different times in the studies. All three studies that measured physiological variables of heart rate demonstrated significant changes. Only one of the studies (Tyler et al 1990) demonstrated an increase in heart rate and this was to be expected. This study used a back rub, a massage technique which increases the heart rate. Although this was not a true massage and was not treated as such in this study, the findings are important as this study examined the effects of massage on ventilated patients (few have), and it established the effect of a limited massage on the critically ill patient who may be very unstable. This study suggested that the first minute of a massage may cause the patient to become unstable. Two other studies (Field et al 1998, Hayes and Cox 2000) demonstrated a reduction in heart rate which could suggest that the intervention was relaxing.

Labyak and Metzger (1997) undertook a meta-analysis of nine studies which examined the physiological outcomes of effleurage back rubs in relation to their relaxation effects. Studies, which used massage of at least three minutes of duration and included outcome measures of heart rate, blood pressure and respiratory rate, were incorporated in the analysis. They found that massage lasting for three minutes were associated with an eleven percent reduction in heart rate and blood pressure and conclude that three-minute massages should be used to promote relaxation.

A recent publication by Richards et al (2000) presented a comprehensive systematic review of twenty two articles, which examined the effects of massage on relaxation, comfort and sleep in acute and critical care. They found that the most consistent effects of massage were a reduction in anxiety, with eight of ten studies reporting a significant decrease in anxiety. Most of these studies were in acute care (such as oncology, hospice care) and not in critical care. This is why the conclusions of the review are different from the findings in this study. A reduction in physiological indicators of relaxation (heart rate, blood pressure and respiratory rate) in seven of the ten studies was also noted. Although these findings do suggest some relaxing effects of massage Richards et al (2000) conclude by suggesting further research into the effects of massage in acute and critical care is necessary. This review highlighted one problem of examining similar research studies which do not use similar subjects. Richards et al (2000) have classed most research studies as acute and critical care. However studies such as Meek (1993), was undertaken in a hospice and Weinrich and Weinrich (1990) was undertaken in an oncology unit. These studies have different outcome measures and use different patient populations to those in critical care which are usually restricted in movement and speech due to ventilation.

The tables demonstrate the diverse range of outcome measures which have been utilised. In many cases this has resulted in the need to clarify outcomes as numerous different tools have been used to measure similar outcomes. There is a need to use different measures dependent on the study population and by using different measures other discreet effects of massage may be exposed. All the measures chosen were appropriate for the study being undertaken and the patient population. However some measures were of poorer quality than others. The measurement of physiological variables such as heart rate and blood pressure were measured concisely using specialised equipment, some psychological variables such as anxiety and mood were also measured using specially designed and tested tools, however spontaneous comments and the measurement of pain are more difficult to measure and to verify the response, even though these outcome measures appear to be important indicators in complementary therapies. It is important to use reliable and valid tools to collect data and examining the use of previously used outcome measures can help to determine which measures to use in future work.

Summary

The increasing numbers of empirical studies undertaken in the area of massage have generally been inconclusive in their results. Some studies have demonstrated positive effects (Field et al 1992, Hayes and Cox 2000) whilst others have not demonstrated any differences (Sims 1986, Groer et al 1994) between those patients who received massage and those who did not. This group of studies showed that it is possible to measure the effects of massage using physiological and psychological indicators and there were no reports of any adverse effects, suggesting that massage is safe to use. The majority of the studies utilised an experimental methodology but the quality of these need to be improved in order to produce scientifically credible results. Other methods of exploring the effects of massage remain necessary. The increasing body of research and examination of it will help to focus future research.

2.6. Aromatherapy Massage

The following section explores the history of aromatherapy, and examines the introduction of aromatherapy into nursing, reviewing the limited research that has been undertaken. A thorough search of the literature was undertaken which elicited a total of 60 papers. The literature was divided into two main sections, anecdotal literature n=31(52%, table 2.18) and empirical studies n=29 (48%, table 2.19). The empirical studies were grouped under the following headings; aromatherapy studies in midwifery (table 2.20), aromatherapy studies in the care of the mentally ill (table 2.21), aromatherapy studies in critical care (table 2.22) aromatherapy studies in oncology (table 2.23), aromatherapy studies in the elderly (table 2.24) and other aromatherapy studies (table 2.25). Both physiological (table 2.26) and psychological (table 2.27) outcome measures that were used in the empirical studies were also reviewed.

2.6.1. Historical Perspectives

Aromatherapy is an ancient art. The history of its use dates back many thousands of years. Evidence for the use of essential oil is said to date back to the tomb of Tutenkahmun in the 14th century BC and the Egyptians were known to use aromatic oils of frankincense and myrrh to preserve bodies for reincarnation (Price 1993). At this time India is also thought to have been using plant extracts as medicines and one of the oldest known books on plants "Vedas" is Indian. Both India and Egypt used and developed aromas for religious and medicinal purposes and many groups burnt resins in religious, mystic and purification ceremonies. The development of the use of plants for healing began to spread across Europe until its use eventually reached Britain in the 15th century. The earliest records of the use of plants for healing in Britain date from 1653, when Nicholas Culpepper wrote his famous herbal from which people still quote today. However from this time the industrial revolution was thought to be responsible for the decline in the use of herbs as people moved into industrial towns to seek work.

By 1896, chemical science was becoming important and drugs were beginning to be synthesised. It was also at this time that people became re-aroused to the uses of natural medicines, as they became disillusioned with modern medicines (Baldwin 1993). It was during this period, in the early 20th century that the term aromatherapy was introduced. Rene-Maurice Gattefosse was thought to have developed the term aromatherapy, and he published a book of his early research into essential oils and aromatherapy (Gattefosse 1937).

It was not until the late 1950s that the term and use of aromatherapy reached Britain. Marguerite Maury moved to Britain from France and promoted the use of aromatherapy via beauty therapists who were qualified in massage, hence the link between aromatherapy and massage. The main application at this time was to treat stress and skin conditions by massaging pre-mixed oils into the skin. The perfume industry kept ingredients a closely guarded secret, for commercial reasons. The use of aromatherapy at this time was mainly constrained to the beauty industry and small studies were usually undertaken on friends to evaluate the effects of oils.

Dr. Valnet also became known as a leading authority on aromatherapy due the work he undertook in France in the 1960s. Aromatherapy has been used medicinally in France for many years and many people believe that it is due to the work of Valnet (Valnet 1964) that aromatherapy is now recognised as a therapy in its own right (Tisserand 1994).

The term aromatherapy is the use of essential oils for therapeutic purposes. Price (1993) has suggested that the definition of aromatherapy is a therapy using essential oils extracted from plants and not the plants in their entirety (ie herbalism). She supported this difference by claiming that the history of aromatherapy is connected to the use of whole plants for medicinal use and essential oils were not introduced until the 1950s. The BMA (1993) define aromatherapy as "massage with external use of plant essential oil diluted in a base oil of vegetable origin". This is not a strict definition but is a common one as most people use essential oils in the form of a massage. However, there are many ways of using essential oils and aromatherapy basically means a therapy of aromas. The definition of aromatherapy used by Price (1993) will be used in this review; "the controlled use of essential oils to maintain and promote the health and vitality of the spirit, the emotions and the physical body". This definition can include many practical methods of application, such as inhalation, baths, compresses, self application and massage, and is a fuller definition than that suggested by the BMA, which does not recognise other methods of using essential oils.

2.6.2. Essential Oils

A review of literature regarding essential oils elicited few articles. Most of the literature has been found within books. This is mainly due to the limited research that has been undertaken in essential oils and more specifically examining essential oils.

Essential oils are complex cocktails of many different naturally occurring components; there are several different kinds of terpenes, alcohols, phenols, ketones and esters within each oil, and these vary from harvest to harvest and from plant to plant. The actions of any whole essential oil are difficult to predict due to this complicated make-up. There is no direct simple relationship between the chemical constituents and the therapeutic qualities of an essential oil and this also means there is no simple way of determining any hazardous effects. Work undertaken in France attempted to classify essential oils based on their chemical make-up and attempted to determine the properties that each of the oils should display.

2.6.2.1. Metabolism of essential oils

The body is thought to metabolise essential oils in the same way as drugs. There are however concerns with this theory when using essential oils in clinical practice due to their interactions with drugs and for this reason medical practitioners are sceptical about their use. Essential oils are fat soluble and are absorbed via cell membranes which are rich in lipids. They are readily absorbed into the nervous system as it is rich in lipid, and the liver via the bloodstream. The oils pass more slowly into muscle fibres and adipose tissue. However because adipose tissue acts as a reservoir for fat-soluble molecules, essential oil molecules that reach it will be stored there for some time. This is important to consider when examining the effects of essential oils, and the dose used and the number of times it is applied should be considered and made explicit. Some oils are thought to bind with plasma albumin and this is thought to reduce the effects of the oil initially as the albumin mops up the oil molecules but it also prolongs the amount of time the oil remains in the body. Balacs (1992) suggested that in patients with renal impairment who have a low plasma albumin lower concentrations of oil should be used, to prevent high doses of circulating oil molecules. This is also important if drugs and essential oil are competing for to bind with plasma albumin, as drug molecules will be left to circulate freely in the blood. This could potentiate the action of the drug and lead to possible overdose or adverse effects. Balacs (1991) has also suggested that essential oils may regulate immune function by lodging in the membrane of leucocytes, or affect nerve function in the same way as anaesthetic drugs. Essential oils are excreted mainly via the kidneys, although some constituents are expelled by means of expiration. The actions of the essential oils can be enhanced by the use of massage, which increases circulation. Any skin that is damaged or diseased also increases the rate of absorption. It is important to remember that the oils are also inhaled during a massage.

2.6.2.2. Absorption of essential oils

Research into how and why essential oils work is limited, although increasing. The relaxation effects of many essential oils may be attributed to their chemical properties or to the method of administration (particularly massage) or a combination of the two factors. Alternatively the effects may arise from preference of smell or the oils may work directly on the central nervous system. Essential oils may exert their effect in two main ways, through the skin and through the nasal passages. They can also be taken orally, although this method was not used in this study.

The sense of smell is extremely sensitive in humans. It can detect over 100,000 odours (Carola et al 1992). Olfaction is classified as one of the special senses with odour perception being transmitted directly to the brain via the first cranial nerve. For an aroma to be detected the molecules of the substance must be volatile. In aromatherapy, volatile essential oil molecules pervade the air and some enter the nostrils and are picked up by the cilia at the vesicular end of the olfactory receptors. The cilia are surrounded by fluid secreted from the supporting cells and the olfactory glands in which the aromatic molecules dissolve prior to stimulation of the receptor sites. There has some been work examining the effects of odours on the brain which suggest that odour effects mood, creativity and perceived health (Knasko 1992). Manley (1993) found that some essential oils achieved the expected responses including bergamot. The results of these studies seem to suggest that essential oils do have an effect on mood, although they are small studies with little experimental control.

The skin acts as a protective cover for the internal organs and prevents body fluids from being lost and harmful substances such as micro-organisms from gaining entry. It is virtually waterproof but allows the passage of certain molecules including essential oils. Also the skin is an important sensory organ. The epidermis is the outer layer of skin, which has no blood vessels but is very thin. Beneath the epidermis is the dermis, which is a strong connective mesh of thick protein collagen fibres to make the skin tough. The dermis contains blood vessels, which carry the fat soluble essential oil molecules around the body, lymphatic vessels, nerve fibres and hair follicles.

A variety of sensations are perceived by the skin due to sensory receptors, these include pain, pressure and temperature. Massage is thought to increase the rate of systemic absorption of essential oils due to the increased blood flow. The legs (used in this study) are less permeable than other areas but due to the presence of hairs these facilitate the passage of molecules as they travel along the hair shaft to the dermal layer.

Debates regarding the effectiveness of essential oils concentrate on the constituents of essential oils and the method of administration (especially massage) to determine the reason for their effects. The actions of the essential oils can be enhanced by the use of massage, which increases circulation. There is some research, which has examined the ability of essential oil molecules to be absorbed by the skin (Jager et al 1992 and Weyers and Brodbeck 1989). Jager et al (1992) found in a trial of lavender oil used in massage that constituents of the oil were in the blood after five minutes and had reached a peak at 20 minutes. There were no traces of lavender oil in the blood after 90 minutes. This could suggest that there are no long-term benefits to the use of essential oils and there may be other factors that need to be investigated. Massage is thought to increase the rate of systemic absorption of essential oils due to the increased blood flow, but also the molecules are probably more readily vaporised and therefore inhaled to take effect on the body. The legs are less permeable for the passage of essential oils compared to palms of the hands and soles of the feet, but if they are hairy this facilitates the passage of molecules as they travel along the hair shaft to the dermal layer.

3.6.2.3. Safety of essential oils

There remains a great deal of literature about essential oils from various sources, (including the perfume and pharmacology industry) that needs to be collated in order to fully understand essential oils and therefore they should be used with care. Some studies have shown that there are increased effects of oils with increased doses (Jori et al 1969, Kovar et al 1987). Practitioners suggest that dose should be body weight related in a similar way to drugs.

There is also some evidence to suggest that when measuring dose by drop size, that the drop size of the same oils (manufactured by different companies) are different, thus resulting in different doses (Olleveant et al 1999), and that the ability to achieve a similar dose every time, measured by drops is not possible. This would affect the safety of oils.

Recent accounts of the public using readily available essential oils have led to concerns regarding the safety of their use (Downer 1999) and have led to calls for increased education in the mechanism of action of essential oils (Price 1998). Avis (1999) suggested that an understanding of the chemical components of each oil is a necessary part of safe and effective aromatherapy practice. She also makes explicit the need for training to include appropriate curriculum relating to the clinical use of essential oils, which should be determined by suitable bodies such as the Aromatherapy Organisations Council. Reputable oils should also be used which conform with the guidelines within the Control of Substances Hazardous to Health (COSHH). Tiran (1995) stated that no oil should be used continuously for more than three weeks.

2.6.2.4. Essential Oil of Bergamot (Citrus Bergamia)

Bergamot essential oil was selected as the oil of choice for use in this study. It was chosen for its properties of being relaxing, sedative and anti-depressive (Tisserand 1994). Some recent studies (Occhiuto and Circosta 1996 and 1997) have demonstrated anti-arrhythmic and anti-anginal effects of bergamottine (extracted from bergamot oil) in guinea pig and rat. It is inexpensive to use but has not been extensively researched. It was also chosen as a smell that both men and women would like and is not overpowering, but light and pleasant. The Latin name for the oil is 'citrus bergamia' and it belongs to the plant family 'rutaceae'. The essential oil is expressed from the peel of the fruit that grows in Italy. Expression is the method of extraction used mainly for citrus fruits, where the essential oil is located in little sacs just under the surface of the rind and is pressed out. The fruit resembles a pear shaped orange. The scent is sweet and citrus, but has a warm floral quality.

The chief chemical constituents found in bergamot oil are;

Alcohols	geraniol (s) Linalool (l) Nerol (s) Alpha-terpineol (s)
Aldehydes	citral (l)
Esters	linayl acetate (m)
Ketones	none
Oxides	none
Phenols	none
Terpenes	camphene (s) Limonene (s) Pinene (s)
Coumarin	bergapten (t)

l = large amount
m = medium amount
s = small amount
t = trace

The constituents in bergamot oil that are known to have therapeutic effects are;

Limonene – sedative

Bergapten – photoxic

Linalool – antiseptic

Citral – antiseptic

Geraniol - antiseptic

Bergamot is phototoxic. It is the coumarins (which are photosensitisers) in the expressed oils that can cause problems in sunlight (Naganuma et al 1985, Yasui and Hirone 1994). A large study undertaken in 1992 by Bruynzeel et al examined the effects of contact sensitisation of five essential oils on 1032 subjects. It was found that 93 (9%) of subjects were sensitive to oils and he stated that "this shows how important it is to find out whether the patient has previously used essential oils and to patch test". Zaynoun (1977) tested the effects of bergamot oil containing 0.31% bergaptenes and found that skin reactions occurred at 2.5% dilution. Watts (1992) tested bergaptene free bergamot oil to a concentration of 30% dilution and observed no irritation or sensitisation. It is important to patch test the skin when using essential oils to determine any reactions to the oil. In this study all patients were patch tested for any reactions to the oil before it was used within the massage oil.

The oil should not be used immediately before going into the sunlight or exposure to ultraviolet light. Care must be taken when using this oil. Coumarins free bergamot oil was used in this study to ensure that no problems with photosensitivity occurred. Some patients in the study would be near windows where sunlight could produce photosensitivity.

Precautions need to be undertaken when using bergamot oil, as it increases the photosensitivity of the skin. This is due to a substance in the oil known as bergaptene, which helps with tanning but does not protect from burning. Bergamot is often used in sun tanning preparations. Studies (Zaynoun 1977, Moysan et al 1993) have shown that bergapten is phototoxic on human skin, and this causes sensitisation and skin pigmentation when exposed to direct sunlight. It is advisable to use "bergapten free" essential oil of bergamot. It may also irritate sensitive skins.

2.6.3. Anecdotal Aromatherapy Massage Literature

A review of the anecdotal literature elicited 31 articles. These article were reviewed by dividing them into groups relating to the topic they described ie general aromatherapy literature (Armstrong 1986, Westwood 1986, Wise 1989, Wright 1989, O'Byrne 1990, Coxon 1991, Stevenson 1992, Buckle 1993, Trevelyan 1993, Scott 1995, Cerrato 1998, Avis 1999), acute care (Kingman 1991, Tattam 1992, Macdonald 1993, Wong 1998), oncology (Turton 1989), mental handicap (Hanse 1990), midwifery (Swinnerton 1990) and elderly (Passant 1991, Cannard 1995, Brett 1999), table 2.18.

Many authors produced general anecdotal literature relating to aromatherapy which have addressed issues pertaining to the use of essential oils (Buckle 1992, Cerrato 1998, Avis 1999), how to prescribe aromatherapy (Coxon 1991), how to introduce aromatherapy into the clinical area (Wright 1989, Stevenson 1992 and Scott 1995) and described aromatherapy and its value in health care (Armstrong 1986, Westwood 1986, Wise 1989, O'Byrne 1990, Trevelyan 1993).

Other papers have reviewed the use of aromatherapy in relation to clinical areas of nursing. Six papers relating to the use of aromatherapy in acute care were derived from the literature search (Kingman 1991, Tattam 1992, Macdonald 1993, Walsh 1996, Wong 1998, Gibbons 1998).

Table 2.18 Summary of Anecdotal Literature relating to the use of Aromatherapy Massage, presented chronologically.

Author	Speciality
Armstrong (1986)	Defined aromatherapy
Westwood (1986)	Defined aromatherapy
Turton (1989)	Oncology
Wise (1989)	Defined aromatherapy
Wright (1989)	Introduction of aromatherapy into healthcare
Hanse (1990)	Mentally handicapped
O'Byrne (1990)	Defined aromatherapy
Swinnerton (1990)	Midwifery
Coxon (1991)	Prescription of aromatherapy
Kingman (1991)	Acute care
Passant (1991)	Elderly
Armstrong (1991)	Case study
Stevenson (1992)	Introduction of aromatherapy into healthcare
Tattam (1992)	Acute care
Buckle (1993)	Lavender oil
Macdonald (1993)	Acute care
Trevelyan (1993)	Defined aromatherapy
Tobin (1995)	Elderly
Evans (1995)	Oncology
Scott (1995)	Introduction of aromatherapy into healthcare
Cannard (1995)	Elderly
Walsh (1996)	Acute care
Lennox (1997)	Elderly
Howdyshell (1998)	Elderly
Cerrato (1998)	Benefits of aromatherapy
Walsh and Morrissey (1998)	Aromatherapy for stress
Gibbons (1998)	Acute care
Wong (1998)	Acute care
Brett (1999)	Elderly
Avis (1999)	Prescription of essential oils
Cook and Ernst (2000)	Effects of aromatherapy

Three of these articles (Kingman 1991, Tattam 1992, Macdonald 1993) described the use of aromatherapy in intensive care units, and discussed how it can be of benefit to patients. Walsh (1996) described the use of aromatherapy in the management of psoriasis. Wong (1998) presented a case study of a lady she had treated successfully for high blood pressure and arthritis using a variety of different essential oils and

Gibbons (1998) suggested that a study to examine the use of essential oils as pre-medication would be a useful extension of the care received in theatre. She suggested that thay could be used to prevent post-operative nausea and pre operative anxiety and that the use of essential oils could be more cost effective than conventional medicine.

Papers by Turton (1989), Evans (1995) and Hanse (1990) all proposed that aromatherapy massage was useful because of the positive aspects of touch and suggested that aromatherapy enhanced these aspects. Armstrong (1991) presented subjective data based on patients feelings suggesting that aromatherapy is beneficial to patients. One patient commented that they 'feel alive again'. Walsh and Morrissey (1998) and Cook and Ernst (2000) reviewed the use of aromatherapy for the symptoms of stress and anxiety. They used research evidence and presented a case study to demonstrate the effectiveness of aromatherapy.

Six papers were retrieved relating to the use of aromatherapy in the care of the elderly (Passant 1991, Tobin 1995, Cannard 1995, Lennox 1997, Howdyshell 1998 and Brett 1999). Most of these papers suggested that the use of lavender oil vaporised, in the bath or as a massage in the elderly was beneficial by improving sleep, reducing agitation and for reducing hospital smells.

All these articles are descriptive in nature, with some of them relaying important information. However many of the suggestions remain unproven and practice must at present proceed with caution. Much of this early literature suffered criticism due to the lack of clinical trials to substantiate the claims made about aromatherapy (Mills

1993). Therapists who are keen to demonstrate an effect in their area of work have written many articles which include positive comments from patients, but many of these articles are descriptive or anecdotal in nature and have little evidence to demonstrate benefits. It is interesting that all the anecdotal literature relating to the use of aromatherapy have been written by single authors.

However these papers do highlight the need for further work to substantiate comments and have raised issues such as the safety of oils and the need to use essential oils with care because of their differing effects (Buckle 1993). Buckle (1993) explained that although there are many types of lavender oil, their properties may all be slightly different. Within the anecdotal literature there is little evidence to clarify which oils are safe to use and which oils are useful for different problems. There is no evidence to suggest that individual essential oils produce different individual effects and this does require further investigation. Lavender essential oil is the most comprehensively reported essential oil.

Many of the papers have suggested that aromatherapy may be useful for reducing anxiety and have also shown that lavender can be used on the elderly for a variety of reasons including enhancing sleep and masking hospital odours. These ideas need further investigation.

2.6.4 Empirical Aromatherapy Massage Literature

The literature was searched for any empirical studies undertaken in clinical settings and 29 studies were found, table 2.19. These studies were reviewed by grouping them into six clinical settings; midwifery (table 2.20), mentally ill (table 2.21), critical care (table 2.22), oncology (table 2.23), care of the elderly (table 2.24) and others, including rheumatology and community (table 2.25). Studies were also reviewed by physiological outcome measures (table 2.26) and psychological outcome measures (tables 2.27).

Table 2.19 Summary of Empirical Literature relating to the use of Aromatherapy Massage, presented chronologically.

Author	Clinical Speciality
Cawthorn (1991)	Rheumatology
Hardy (1991)	Mentally ill
Wilkinson (1991)	Oncology
Williams (1991)	Oncology
Woolfson and Hewitt (1992)	Critical care
Buckle (1992)	Critical care
Bell (1993)	Mentally ill
Reed and Norfolk (1993)	Midwifery
Burns and Blamey (1994)	Midwifery
Dale and Cornwell (1994)	Midwifery
Stevenson (1994)	Critical care
Dunn et al (1995)	Critical care
Hudson (1996)	Elderly
Corner et al (1995)	Oncology
Cooper (1995)	Oncology
Wilkinson (1995)	Oncology
Brooker et al (1997)	Mentally ill
Lindsay et al (1997)	Mentally ill
MacMahon and Kermode (1998)	Mentally ill
Kite et al (1998)	Oncology
Brownfield (1998)	Rheumatology
Diego et al (1998)	Staff
Wilkinson et al (1999)	Oncology
Basnyet (1999)	Patients with hypertension
Clarke (1999)	Haemodialysis patients
Papadopoulos et al (1999)	Elderly
Walsh and Wilson (1999)	Neurology
Burns et al (2000)	Midwifery
Saeki (2000)	Students

Table 2.20 Aromatherapy Massage Studies in Midwifery

Author	Design	Sample	Methods	Number of interventions	Type of massage	Oil	Measures	Time measures taken	Findings
Reed and Norfolk (1993)	Survey	N = 38 All female in labour	Oil added to bath in labour	1	None	Lavender	**Physiological;** apgar scores, length of labour, amount of analgesia **Psychological;** questionnaires	Post intervention	No adverse effects on neonate Lavender helped in pain relief in more than half of the women and speeded up labour 34 of the 38 women had a normal delivery Most of the women enjoyed the aromatherapy No statistically significant results
Burns and Blamey (1994)	PILOT Evalua-tive	N = 585 All female in labour	Oils used in bath, footbath, inhalation and massage in labour	Unknown	Type of massage unknown Massage undertaken by 8 trained midwives	10 different oils	**Physiological;** use of analgesia, labour time, reduction in nausea **Psychological;** mood	Post intervention	Midwives and mothers enjoyed using aromatherapy and produced positive comments regarding their effectiveness Results suggest a reduction in analgesia , anxiety and labour time but this is not made clear
Dale and Cornwell (1994)	RCT 3 groups	N = 635 All female post natal	Grp1,n=205; usual care Grp2,n=213; synthetic oil added to bath postnatally Grp3,n=217;lavender oil added to bath postnatally Once a day for 10 days	10	None	Lavender	**Physiological;** pain using a VAS scale **Psychological;** mood using a VAS scale	½ hr post intervention	Mothers enjoyed aromatherapy. No statistically significant evidence but aromatherapy group had lower mean discomfort scores

Key overleaf

Table 2.20 Aromatherapy Massage Studies in Midwifery, continued

Author	Design	Sample	Methods	Number of interventions	Type of massage	Oil	Measures	Time measures taken	Findings
Burns et al (2000)	Evalua-tive study	N = 8058 All female in labour	Oils were used singly (not mixed) Methods; massage, drop on pillow, foot bath, drop in bath.	unknown	unknown	10 different oils, rose, jasmine, chamomile, eucalyptus, lemon, mandarin, clary sage, frankin-cense, lavender, peppermint	**Physiological;** Use of pain relief, uptake of intravenous oxytocin **Psychological;** Reported symptoms, Mothers rating of effectiveness of labour Costs	Post intervention	50% of women who used essential oils found them helpful, 14% unhelpful Aromatherapy did reduce the need for pain relief in some women. Lavender and frankincense were the most commonly used oils to relieve pain The use of pethidine as analgesia declined from 6% to 0.2% over the study 1% adverse symptoms were reported Nb a comparison group of 15,799 mothers who had not received aromatherapy was used

Key
RCT = randomised controlled trial
VAS = visual analogue score

Table 2.21 Aromatherapy Massage Studies in care of the Mentally Ill

Author	Design	Sample	Methods	Number of interventions	Massage	Oil	Measures	Time measures taken	Findings
Hardy (1991)	Quasi-experimental 1 group	N = 4 Elderly mentally ill	Vortex air freshener	One continuous intervention for a 2 week period	None	Lavender 5mls/week	**Physiological;** amount of sleep over 24 hours, assessed ½ hourly	½ hour measurements for 2 weeks pre (with night sedation), 2 weeks pre (without night sedation) and 2 weeks post intervention	Night- time sleeping increased Day-time sleeping reduced
Bell (1993)	PILOT RCT 3 groups	N = 30 Anxious/depressed patients	Grp1, n=10; massage without oil Grp2, n=10; massage with lavender oil Grp3, n=10; massage with geranium oil All massages = 1x30 mins	1	Massage of the neck and back undertaken by 2 qualified nurses standardised by time	Lavender or geranium 3 drops in 20mls	**Physiological;** HR, BP, RR **Psychological**; 5 point anxiety scale and a questionnaire	10 mins pre and immediately post intervention	No differences between the groups All patients enjoyed the massage No results from questionnaire
Brooker (1997)	Single case studies Patients acted as own controls	N = 4 Elderly patients with dementia	Patients received a variation of the following 8-12 times, each lasting 30 minutes, over a 3 month period Aroma only, hand massage only, aroma and hand massage and no intervention	32 - 48	Hand and lower arm massage by trained staff, standardised by time	Lavender (dose unknown)	**Psychological**; 6 point agitation scale	Continuous observation for one hour immediately post intervention Measurements taken every minute of this time	Staff suggested that all patients benefited Significant decrease in disturbed behaviour for one patient receiving both aroma and massage procedures, p=0.05

Key overleaf

Table 2.21 Aromatherapy Massage Studies in care of the Mentally Ill, continued

Author	Design	Sample	Methods	Number of interventions	Massage	Oil	Measures	Time measures taken	Findings
Lindsay (1997)	Quasi-experimental Patients acted as own controls 1 group	N = 8 Profound learning difficulties	Patients received 20 consecutive sessions each lasting 20 minutes of massage, relaxation, active therapy (bouncy castle) and snoezelen (a blackened quiet room with visual, audio, tactile and smelling stimuli)	20	Hand massage undertaken by therapist using set protocol and set time	Orange flower, lemongrass and lavender mixed Dose unknown	**Psychological**; concentration, using simple tasks Responsiveness, rated by independent observers	Concentration measured post simple task Responsiveness measured pre sessions, after 10 sessions, after 15 sessions and in the final session	Snoezelen and the relaxation therapies had significantly improved subjects' concentration over time (value of p unknown).
MacMahon and Kermode (1998)	Single subject design	N = 1 Elderly patient with dementia and depression in full time care	An oil burner in the patients room in the morning for 2 months	60	None	Type and dose of oil unknown	**Psychological**; motivational behaviour	Pre for 2 months Post for 2 months Mean weekly scores	Statistically significant improvement in motivational behaviour, p=0.0001

Key
RCT – randomised controlled trial
HR – heart rate
BP – blood pressure
RR – respiratory rate

Table 2.22 Aromatherapy Massage Studies in the care of the Critically Ill

Author	Design	Sample	Methods	Number of interventions	Types of massage	Oil	Measures	Time measures taken	Findings
Woolfson and Hewitt (1992)	CT 3 groups	N = 36 Adults on intensive and coronary care	Grp1,n=12; usual care Grp2,n=12; massage only Grp3,n=12;aromatherapy massage All interventions = foot massage 10 x 20 minutes	10	Foot massage undertaken by researchers at set time Protocol used - unknown	Lavender Concen-tration unknown	**Physiological;** HR, BP, RR, pain **Psychological;** spontaneous comments	Pre, post and ½ hour post intervention	Patients receiving aromatherapy massage showed the greatest decrease in HR, BP, RR, pain and wakefulness compared to patients who received massage only or no treatment (HR reduced by 91%). Only statistical significance for anxiety which decreased in group receiving aromatherapy (no p value indicated)
Buckle (1992)	Blind RCT 2 groups	N = 28 Post cardiotomy patients	Grp1,n=14; lavender augustifolia Grp2,n=14; lavender burnatii 20 minute massage to feet, legs, hands, arms and forehead on 2 consecutive days	2	Massage to feet, legs, hands, arms and forehead, undertaken by investigator at approx. same times using set protocol for movements	2 types of lavender 5%	**Physiological;** HR, BP, RR **Psychological;** semi-structured interviews	Physiological - day 1 and day 2, ? when Psychological – few days later	No changes in HR or BP, Respirations were slower and deeper (not measured reliably therefore read with caution) Lavender burnatii is twice as effective as Lavender angustifolia in reducing anxiety, but mood and coping ability remained similar
Stevenson (1994)	RCT 4 groups	N = 100 Patients one day post cardiac surgery	Grp1,n=25; usual care Grp2,n=25; 20 minute chat Grp3,n=25; massage only Grp4,n=25; aromatherapy massage Grp3 & 4 = foot massage 1 x 20 minutes	1	Foot massage undertaken by researcher at no set time, using standardised movements and times	Neroli 2.5%	**Physiological;** HR, BP, RR **Psychological;** STAI	1 hour and immediately pre intervention 1 and 2 hours post intervention 5 days post intervention	No statistically significant results, but differences existed between the 2 massage groups and the 2 no massage groups

Key overleaf

Table 2.22 Aromatherapy Massage Studies in the care of the Critically Ill, continued

Author	Design	Sample	Methods	Number of interventions	Type of massage	Oil	Measures	Time measures taken	Findings
Dunn et al (1995)	RCT 3 groups	N = 122 Intensive care patients	Grp1,n=40; undisturbed rest Grp2,n=41; massage only Grp3,n=41; aromatherapy massage Grp 2 & 3 massage any area 3 x 20 minutes	1-3	Massage to any area of the body undertaken by 6 trained nurses at no set time Some standardisation of technique and time	Lavender 1%	**Physiological;** HR, BP, RR, neurological status **Psychological;** spontaneous comments	Pre and post intervention	No statistically significant differences in physiological data and no cumulative effects at the end of three therapy sessions Patients in aromatherapy group reported significant improvements in mood and levels of anxiety

Key
RCT – randomised controlled trial
HR – heart rate
BP – blood pressure
RR – respiratory rate
STAI – State Trait Anxiety Inventory (Spielberger et al 1983)

Table 2.23 Aromatherapy Massage Studies in Oncology and Palliative care

Author	Design	Sample	Methods	Number of interventions	Type of massage	Oil	Measures	Time measures taken	Findings
Williams (1991)	Single case study	N = 1 Female post-op mastectomy	Inhalation; 3 drops in boiling water at bedside over night	1	None	Sandalwood	**Physiological;** ability to sleep	Day following intervention	Subject became relaxed and was able to sleep
Wilkinson (1991)	Single case study	N = 1 Female receiving radiotherapy for cancer	Massage to feet and legs	>3	Gentle massage by trained masseur No protocol	not made explicit	**Psychological;** reduction in nausea	Post, time unknown	Patient stopped feeling nauseas
Wilkinson (1995)	RCT 2 groups	N = 51 Patients with cancer receiving palliative care	Grp1, n=25; massage only Grp2, n=26; aromatherapy massage Both groups = body massage x 3 (1 each week)	3	Full body massage undertaken by 3 trained nurses using a set protocol for movements but not for time	Roman chamomile 1%	**Psychological;** RSCL, STAI	RSCL – pre and 1 week post intervention STAI – pre and post every massage	Statistically improved symptoms, reduced anxiety and improved quality of life in group receiving oil ($p < 0.05$)
Corner et al (1995)	Quasi-experimental 3 groups	N = 52 Patients undergoing treatment for cancer	Grp1, n=18; no usual care Grp2, n=17; massage only Grp3, n=17; aromatherapy massage Half hour back massage x 8 (1 each week)	8	Back massage undertaken by trained research therapist Protocol used - unknown	A blend of lavender, rosewood, lemon, rose and valerian 2%	**Psychological:** HAD, QoL and Symptom distress, interviews	HAD & QoL – pre and 1 hour post intervention Interviews – pre and post study	Significant improvement in anxiety scores with essential oils, $p<0.05$ No significant differences for depression
Cooper (1995)	Evaluation	N = 30 Patients with advanced cancer	All received aromatherapy treatment over 9 months Different treatments for each patient	unknown	Part body massage	Blended essential oils	**Physiological;** 10 point pain scale **Psychological;**question naire	Pain – pre and post intervention Questionnaire – post and 9 months post intervention	100% beneficial 44% eases pain and stiffness 86.4% pain decreased after treatment

Key overleaf

Table 2.23 Aromatherapy Massage Studies in Oncology and Palliative care, continued

Kite et al (1998)	Observation	N = 58 Females with breast cancer receiving radiotherapy	Six treatments, one each week	6	1-4 massages to any part of the body determined by tumour site undertaken by an aromatherapist lasting between 15-60 minutes No set protocol for movements or time	Blended essential oils	**Psychological;** Five point scale to measure presenting symptoms, HAD	Pre and post study	Reduction in anxiety
Wilkinson et al (1999)	RCT 2 groups	N = 103 Patients with advanced cancer in a palliative care setting	Grp1, n=57 massage only Grp2, ,n=46 aromatherapy massage Full body massage x 3 (1 each week)	3	Full body massage undertaken by qualified nurses using a set protocol for time and movements	Roman chamomile 1%	**Psychological;** RSCL, STAI	RSCL – pre and post study STAI – pre and post every intervention	Significant reduction in anxiety following each massage $p<0.001$ Improved scores on RSCL Aromatherapy enhanced all scores compared to massage only

Key
RCT = randomised controlled trial
RSCL = The Rotterdam Symptom Checklist (de Haes et al 1990)
STAI = State-Trait Anxiety Inventory (Speilberger et al 1983)
HAD – Hospital Anxiety and Depression Scale (Zigmond and Snaith 1983)
QoL – Quality of Life and Symptom Distress Scale (Holmes and Dickerson 1987)

Table 2.24 Aromatherapy Massage Studies in care of the Elderly

Author	Design	Sample	Methods	Number of interventions	Types of massage	Oil	Measures	Time measures taken	Findings
Hudson (1996)	Quasi-experimental 1 group PILOT STUDY	N = 9 Elderly	Lavender applied to the pillow every evening at bedtime for 1 week	7	None	Lavender (one drop each evening)	**Physiological;** Wakefulness and alertness	Pre intervention – hourly for 1 week Post intervention – hourly for 1 week	Wakefulness and alertness improved in 8 patients
Papadopoulos et al (1999)	Evaluation and attributional analysis	N = 10 (N=6 elderly with physical health problems) N=4 carers)	Aromatherapy over one year	Unknown	Type of aromatherapy used not explicit but the same therapist was used in all cases	Any, blended together	**Psychological;** interviews, semi-structured questionnaire, stress/pain rating scale	Post interventions (ie after one year)	All clients said they benefited and felt more relaxed following aromatherapy Pain/stress levels decreased during and following the aromatherapy sessions

Table 2.25 Other Aromatherapy Massage Studies

Author	Clinical area	Design	Sample	Methods	Number of interventions	Type of massage	Oil	Measures	Time measures taken	Findings
Cawthorn (1991)	Rheumatology	Single group design	N = 20 Inpatients with rheumatoid arthritis	Massage to any area of the body lasting between 10 and 47 minutes	1	Massage to any area of the body (back, hands, feet) undertaken by trained nurses. No protocol	Ylang ylang Lavender, bergamot sandalwood lemon, fran-kincense peppermint Used in a combination of 2-3 Dose unknown	**Psychological;** Questionnaire Patients comments	Immediately post intervention	Comments suggested effective in reducing anxiety and helping patients to sleep and reduce pain
Brownfield (1998)	Rheumatology	Quasi-experimental 3 groups PILOT	N = 9 Inpatients with rheumatoid arthritis	Grp1; control Grp2&3; 10 minute massage to neck and shoulders on two consecutive evenings. Lavender oil used once, on alternative days for each group	2	Massage to neck and shoulders, not known by who, lasting 10 minutes between 9pm and 10pm	Lavender Dose unknown	**Physiological;** VAS to measure pain and sleep **Psychological;** Semi-structured interview, VAS to measure well-being	Pre and post intervention	Patients reported positive effects following the massage. Over half expressed a desire to receive further massage

Key overleaf

Table 2.25 Other Aromatherapy Massage Studies, continued

Author	Clinical area	Design	Sample	Methods	Number of interventions	Type of massage	Oil	Measures	Time measures taken	Findings
Clarke (1999)	Haemodialysis patients	Quasi-experimental 1 group, patients acted as own controls PILOT	N = 21 Patients receiving haemodialysis	Vaporised for 4 hours on three alternative afternoons	3	None	Mixture of lavender, lemon, rosewood, cedarwood Dose unknown	**Psychological;** SRRS, health assessment questionnaire and reflective journals	SRRS, health assessment and reflective journal – daily Health assessment - 1 month post trial	Patients expressed feeling calmer and more relaxed 6% reduction in utilisation of non productive coping strategies and 6% reduction in symptoms of stress post trial
Walsh and Wilson (1999)	Neurology	Quasi-experimental PILOT	N = 4 Adults on long stay neurology ward	Aromatherapy, reflexology, aromatherapy & reflexology and relaxation Five, 1 hr sessions of each therapy once a week for 5 weeks	5	Massage mainly to the back. Masseur - unknown Protocol and time - unknown	Lavender, rosemary and tea tree mixed 2 drops of each in 15mls almond oil	**Physiological;** Verbal pain scale (0-5) Perceived physical health scale (0-100) **Psychological;** Mood level scale (0-100) Questionnaires; GHQ 12, MHLC, Marlowe-Crowne Scale	Mood – 2 weeks prior to intervention Daily – pain and mood Questionnaires - weekly	Patients expressed that they had received considerable benefit from each therapy Significant difference in the GHQ12 in those receiving aromatherapy & reflexology and baseline ($p=0.03$)
Basnyet (1999)	Private healthcare facility	RCT 2 groups PILOT	N = 20 Hypertensive patients (average blood pressure 140/80) attending a natural health clinic	Grp1,n=10; massage only Grp2,n=10; aromatherapy massage Five massages lasting 45 minutes over six weeks	5	Whole body massage by therapist using a set protocol for time and movements, undertaken at the same time of day	Ylang-ylang, clary sage and marjoram mixed 1 drop of each in 15mls grapeseed oil	**Physiological;** blood pressure, questionnaire	post 1st massage and post 5th massage	Hyper-tension reduced in over half of patients in both groups

Key overleaf

Table 2.25 Other Aromatherapy Massage Studies, continued

Author	Clinical area	Design	Sample	Methods	Number of interventions	Type of oil	Oil	Measures	Time measures taken	Findings
Diego et al (1998)	University Medical School	RCT	N = 40 Staff	Grp1,n=20, lavender oil; Grp2,n=20, rosemary oil 3 drops on a cotton dental swab in a plastic vial held 3 inches from the nose for 3 minutes	1	None	Lavender 10% and Rosemary 10%	**Psychological;** VAS (0-10) for mood Maths computation STAI POMS	Pre and immediately post intervention	Aromatherapy had a positive effect on mood Both groups felt significantly more relaxed ($p<0.001$) and less anxious ($p<0.05$) Lavender made staff feel drowsier whilst rosemary made staff feel more alert
Saeki (2000)	Nursing college	RCT	N = 10 Female students (aged 19-21), acted as own controls	All received; no footbath, footbath for 10 minutes without oil, footbath for 10 minutes with oil in random order	3	None	Lavender 0.05%	**Physiological;** heart rate, finger tip blood flow, respiratory rate	Data collected for 20 minutes continuously for each subject for each condition from 3 mins before beginning to 7 minutes after	No changes in heart rate or respiratory rate Significant increase in blood flow Foot bath with lavender causes small but significant changes in autonomic activity

Key
RCT – randomised controlled trial
VAS – visual analogue scale
SRRS – Social Readjustment Rating Scale (Holmes and Rahe 1967)
GHQ-12 – General Health Questionnaire 12 (Goldberg 1992)
MHLC – Multidimensional Health Locus of Control (Wallston et al 1978)
STAI – State Trait Anxiety Inventory (Spielberger et al 1983)
POMS – Profile of Mood States (McNair et al 1971)
Marlowe-Crowne Scale (Crowne and Marlowe 1960)

The group of tables demonstrate the diverse nature of research that has been undertaken in aromatherapy massage.

Previous surveys (NHS Confederation 1998) have shown that midwives are one of the largest users of aromatherapy but four papers demonstrated the relatively small amount of aromatherapy research undertaken in midwifery. All four papers accumulated mainly subjective data and this was one of the main criticisms of research into aromatherapy. Only one study was a randomised controlled trial and the methodology in all of these studies was poor. Dale and Cornwell (1994) recognised this problem "there seem to be few if any, previous systematic studies which evaluate the clinical use of lavender oil (or other oils used in aromatherapy) against a control".

Many of the randomised controlled trials in massage and aromatherapy have centred on the use of aromatherapy in critical care areas including cardiac intensive care. Some methodological problems were apparent. Stevenson (1994) used four study groups in her trial, but did not subject them all to the same data collection methods. Only two of the groups that received massage were followed up by a questionnaire on day five. This biased the data collected from the questionnaires.

Many of the problems within the massage research are apparent in aromatherapy massage research, including the number of massage interventions, the length of the massage, the area massaged, but also include other problems regarding the use of essential oils. These include, the oil concentration, how to administer the oil, patients body size and skin type.

The number of massage interventions varied in the studies from one to ten. Some findings are misleading as other studies that have not used massage, have used up to sixty interventions. This suggested that it is easier to administer the oils more often when massage is not used. Wilkinson et al (1999) found that the power of significance in relation to anxiety increased when patients received three massages ($p<0.0001$) compared to one massage ($p<0.001$). Corner et al (1995) found that patients who received a course of aromatherapy massage (a total of eight massages over eight weeks) had significantly reduced anxiety scores ($p<0.05$) compared to those patients who received a course of massage only or usual care. The study undertaken by Kite et al (1988) found significant improvements in anxiety ($p<0.001$) in patients who completed a course of massage only or aromatherapy massage (a total of six massage over six weeks). Both Corner et al (1995) and Kite et al (1988) used blends of essential oils that were mixed by the therapist specifically for each patient.

The duration of the aromatherapy is important but difficult to determine when using essential oils because the length of effectiveness of the oils is not known (ie the half-life). The method of administering the oil will also have an effect on this. The duration of the massage varied in the studies from twenty minutes up to any length of time (the time was not specified). However many of the aromatherapy massages lasted 45 minutes which is longer than the duration in the group of massages only studies.

The method of administering the aromatherapy is important. Not all the research studies have used massage to introduce the aromatherapy, but studies were included if the outcome measures were comparable, ie by including physiological and psychological outcome measures. Twenty (69%) of the studies used aromatherapy massage whilst baths and vaporisers were used in the remaining studies as a method of administration. Half (n=2) of the studies in midwifery used massage and the remaining studies used mainly baths. In all other studies when massage was not utilised, inhalation via a burner or vaporiser was used. The issue of administration of essential oils is one which needs addressing in order to determine the most effective method of application. If using a burner or vaporiser were as effective as a massage this would be more cost effective as trained masseurs would not be required.

The movement procedure used to administer the massage may need to be clearly defined so that masseurs can all use the same procedure. Some of the studies followed set protocols whilst others did not. In order for the study to produce clear findings the massage procedure must be in accordance with the research methodology. The person administering the therapy must be made explicit. Studies that use essential oils require relevant qualified personnel.

In the majority of studies the feet or back are used as areas to massage, as these are most accessible. However when using essential oils it is also important to examine the patients skin. The age of patients need to be considered when comparing the results because the essential oils will be absorbed more readily through younger skin. In elderly patients the outcome of the oils may be impaired by taking longer to be absorbed through the skin resulting in a different effect time.

The quality of essential oils used in this group of studies was not accounted for even though they are regarded as medicinal products. The quantity of essential oil used within the studies varied from 1% solution to 10% solution. For massage purposes the concentration used was between one and five percent. Many of the studies did not mention the concentration. This area needs more research to determine the therapeutic dose. The body index of patients also requires consideration in order to determine correct dose but this was not mentioned in any studies.

When using essential oils with massage, patient choice is important as some patients do not like certain smells. Therapies may be more effective if patients can choose which area is massaged, for how long and have a choice of which essential oils to use. Brooker (1997) emphasized the need for individualised assessment and treatment plans for patients. This study also made a claim for using single case methodology to enable individual responses to be examined and suggested it is a more illuminating methodology than group designs. Lindsay et al (1997) suggested that by using a single case study approach adopted for each individual may have been more useful in demonstrating beneficial effects of the therapies.

Studies were reviewed to determine the effectiveness of aromatherapy massage on relaxation and both physiological (table 2.26) and psychological (table 2.27) measures to determine this were utilised. Many different outcomes measures have been used and they are reviewed within the tables.

Table 2.26. Physiological Outcome Measures used in studies of Aromatherapy Massage.

MEASURE	STUDIES	RESULTS
Heart Rate	Woolfson and Hewitt (1992), Bell (1993), Buckle (1993), Stevenson (1994), Dunn et al (1995), Saeki (2000)	No differences found between groups
Blood Pressure	Woolfson and Hewitt (1992), Bell (1993), Buckle (1993), Stevenson (1994), Dunn et al (1995), Basnyet (1999)	Basnyet (1999) demonstrated a reduction in blood pressure in those who received massage or aromatherapy massage All other studies showed no differences between groups
Respiration Rate	Woolfson and Hewitt (1992), Bell (1993), Buckle (1993), Stevenson (1994), Dunn et al (1995), Saeki (2000)	No differences found between groups
Pain	Woolfson and Hewitt (1992) and Reed and Norfolk (1993) – verbal reports Burns and Blamey (1994), Burns et al (2000) – analgesia used Dale and Cornwell (1994), Brownfield (1998) - visual analogue scale Cooper (1995) – 10 point pain scale Walsh and Wilson (1999) – 5 point verbal pain scale Papadopoulos et al (1999) – rating scale	Woolfson and Hewitt (1992) , Cooper (1995), Papadopoulos et al (1999)patients in the aromatherapy and massage groups reported less pain. No substantive evidence that aromatherapy reduces the need for analgesia. Midwifery studies showed a reduction in pain in all groups receiving aromatherapy
Sleep	Hardy (1991), Williams (1991), Woolfson and Hewitt (1992) – observation, Brownfield (1998) – visual analogue scale	Three studies found that patients slept better following aromatherapy. Brownfield (1998) found no difference. There are many difficulties measuring sleep
Length of labour	Reed and Norfolk (1993), Burns and Blamey (1994)	No conclusive evidence. Verbal reports from mothers and midwives that some essential oils (clary-sage and lavender) speed up labour

Table 2.27. Psychological Outcome Measures used in studies of Aromatherapy Massage

MEASURE	STUDIES	RESULTS
Spontaneous Comments/interview and/or questionnaires	Cawthorn (1991), Woolfson and Hewitt (1992), Bell (1993), Reed and Norfolk (1993), Stevenson (1994), Dunn et al (1995), Corner et al (1995), Cooper (1995), Brownfield (1998), Wilkinson et al (1999), Papadopoulos et al (1999), Clarke (1999), Basnyet (1999), Burns et al (2000)	All comments were positive. The information collected was qualitative and no statistical analyses were undertaken.
Anxiety	Cawthorn (1991), Woolfson and Hewitt (1992), Buckle (1993), Stevenson (1994), Dunn et al (1995), Wilkinson (1995), Diego et al (1988), Wilkinson et al (1999) used STAI Corner et al (1995) and Kite et al (1998) used HAD	All patients felt less anxious Anxiety showed a decrease and reached significance in most studies The decrease in anxiety was enhanced when more massages were received and the decline was further enhanced by aromatherapy massage.
Symptoms	Wilkinson (1995), Wilkinson et al (1999) used RSCI Corner et al (1995) used symptom distress scale Kite et al (1993) used 6 point scale Burns et al (2000) – self report	Symptoms improved in all studies. Wilkinson (1995) demonstrated significant improvement in physical symptoms ($p=0.003$) Wilkinson et al (1999) demonstrated significant improvement in all scores ($p<0.05$ for physical symptoms)
Mood	Burns and Blamey (1994) used personal evaluations Dale and Cornwell (1994) used VAS Brooker et al (1997) used 6 point agitation scale Walsh and Wilson (1999) used mood level scale 0-100 Diego et al (1998) used POMS	All studies reported some improvement in mood No statistically significant results from any studies.
Quality of life, psychological distress	Corner et al (1995) used scale for cancer patients (Holmes and Dickerson 1987) Walsh and Wilson (1999) used GHQ 12	No differences between the groups
Behaviour	Walsh and Wilson (1999) used Marlowe-Crowne scale Lindsay et al (1997) used videotapes and simple tasks to measure concentration and enjoyment.	No significant differences between groups
Stress	Clarke (1999) used the SRRS, a health assessment questionnaire and reflective journals to assess stress	No significant changes in patients before and after the aromatherapy, but patients felt calmer and more relaxed

Key
STAI – State Trait Anxiety Inventory (Spielberger et al 1983)
HAD – Hospital Anxiety and Depression Scale (Zigmond and Snaith 1983)
POMS – Profile of Mood States (McNair et al 1971)
GHQ 12 – Genera Health Questionnaire (Goldberg 1992)
SRRS – Social Readjustment Rating Scale (Holmes and Rahe 1967)

The recorded time of the outcome measures needs consideration particularly in relation to the use of essential oils. The half-life of essential oils is unknown. It is therefore difficult to collate the therapeutic effect. The concentration of oil used, the method of application and the condition of the patients skin all need deliberation. Case studies would be a useful tool to determine the optimum effects for patients which could then be useful in future work. Outcomes were measured from between immediately post aromatherapy massage up to one-year post aromatherapy massage. It is interesting that physiological indicators were measured over a much shorter time frame than the psychological indicators.

Studies have used different outcome measures dependent on the group of subjects. This is taken into consideration when reviewing the studies. Some of the studies do measure similar variables, for example pain. Many of the studies do not have transferable outcomes specific to the group of patients studied; symptom relief in cancer patients is not relevant to critically ill patients. Also, it was difficult to compare studies that measured the same variables using different tools making it difficult to compare findings or results. A variety of essential oils of different doses were used, with several methods of application and varying lengths of time to record measured changes. For example some recordings were made after the first minute of the massage whereas others were made after half an hour. It was therefore difficult to compare these findings.

All of the studies have suggested an improvement in anxiety following massage or aromatherapy massage. Several essential oils were used in the studies and an improvement was seen in all of the studies, which may suggest that the type of essential oil may not be important. The actions of essential oils are mainly unproven and studies are based on anecdotal literature regarding their uses. The dose of essential oil differed, as did the duration of massage and the surface area being massaged. It appeared therefore that the duration of the massage does not have an effect on outcome. However there is some evidence to suggest that the number of massages received does have an effect on outcome. Corner et al (1995) found that when asked, patients would choose to have more than one massage. Patients in her study felt that the effects were cumulative and they needed time to build up a relationship with the massage therapist. The studies using a specially prepared essential oil mix for each patient showed better results and it would be interesting to examine patient/therapists choice of oils and area massaged to determine this effect.

<u>Summary</u>

In summary, the literature review has collated all of the available evidence regarding the use of massage only or aromatherapy massage in clinical practice, has highlighted methodological problems associated with demonstrating an effect, and has revealed many variables used to measure outcome in the studies. Aromatherapy has been used as an adjunct to nursing care most commonly to relieve problems such as insomnia, pain and anxiety.

Some of the variables chosen to measure these problems such as sleep and pain are inherently difficult to measure reliably and this has led to increased scepticism of complementary therapies and their effectiveness. However studies that have examined anxiety, have been able to demonstrate favourable results in many different areas of healthcare. It appears that two main types of work are required to examine these effects, experimental studies and research using case study methodology.

There has been limited work in the field of aromatherapy, and with increasing popularity regardless of proven benefits or side effects, it is important to ensure that further research is undertaken to add to the limited body of knowledge and bring to the fore, areas for future work. This scientific study was undertaken to determine the effects of using massage and aromatherapy massage on critically ill patients. Earlier studies have examined physiological variables and have found little evidence of any effect. However studies that have examined psychological variables such as anxiety have been able to demonstrate effects. This is an area that had been neglected in critical care even though patients are subjected to a variety of stressful events. This study has incorporated psychological variables of anxiety, depression and quality of life to determine any effects in critically ill patients.

The comprehensive literature review has enabled the methodology to be moulded based upon these findings. An experimental methodology was chosen which some would argue does not allow all aspects of complementary therapies to be explored. However due to the limited evidence available it was necessary to produce some scientific evidence which could be expanded and utilised in future work. The use of experimental methodology enhanced the power of the study and the variables measured, enabled clarification of previous work. It was important to clarify the massage technique, duration of massage and the time for recording outcome variables and this study has highlighted this as an area which requires further exploration. It was felt that this study would add substantial information to the area of aromatherapy massage.

3 STUDY DESIGN AND METHODS

3.1 Introduction

The main purpose of the study was to test whether massage and aromatherapy massage were relaxing therapies to use for critically ill patients who were in intensive care demonstrated by a reduction in blood pressure, reduction in heart rate, reduction in respiratory rate and a reduction in the quantity of analgesic and anaesthetic drugs. The study also examined the effect of the therapies on the level of depression, anxiety and the quality of life of patients following discharge from intensive care and one-month post discharge from intensive care. This chapter described the research methods employed in the study together with the theoretical justification for their use.

The study used a randomised controlled experimental methodology comprising of three groups; a control group and two experimental groups. Subjects were randomly assigned to one of the groups. The study procedure was carried out and data collection was undertaken over the course of the study. The methods utilised to develop and pilot the instruments are discussed, and an account given of the practical management of sampling, recruitment, data collection, data management and analysis.

3.2. Study Aims

The aim of the study was to investigate the use of massage only and aromatherapy massage in patients who were critically ill, against a control group of patients who received no study intervention. It was predicted that the interventions singly and together would reduce blood pressure, heart rate and respiratory rate. They would also reduce the pain experienced by patients, demonstrated by the use of less analgesia and a reduction in pain scores, and patients would feel more relaxed and able to sleep demonstrated by the use of less anaesthetic drugs and a reduction in sedation scores.

It was predicted that following discharge from intensive care these interventions would make patients feel less depressed and less anxious as measured by the Hospital Anxiety and Depression (HAD) Scale (Zigmond and Snaith 1983) and results would demonstrate an enhanced quality of life for patients, as measured by the Short Form 36 questionnaire (SF-36, Ware and Sherbourne 1992). It was also predicted that one month following discharge from intensive care that patients would continue to feel less depressed and less anxious and would continue to have an enhanced quality of life, as measured by the HAD scale (Zigmond and Snaith 1983) and the SF-36 (Ware and Sherbourne 1992).

3.3. Hypotheses

1. Patients who are critically ill and in intensive care that have received massage only or aromatherapy massage will demonstrate a reduction in blood pressure, heart rate and respiratory rate compared to those patients who did not receive massage or aromatherapy massage.
2. Patients who are critically ill and in intensive care that have received massage only or aromatherapy massage will require a reduced quantity of analgesic drugs than those who did not receive massage only or aromatherapy massage.

3. Patients who are critically ill and in intensive care that have received massage only or aromatherapy massage will require a reduced quantity of anaesthetic drugs than those who did not receive massage only or aromatherapy massage.
4. Patients who are critically ill and in intensive care that have received massage only or aromatherapy massage will have reduced anxiety and reduced depression scores, and demonstrate an improved quality of life on discharge and at one month discharge from intensive care compared to those patients who did not receive massage only or aromatherapy massage.

In order to address the study's first hypothesis the dependent variables of heart rate, systolic blood pressure, diastolic blood pressure and respiratory rate were measured before and after each massage only or aromatherapy massage and at corresponding times for patients in the control group.

To test the study's second hypothesis and determine whether it was possible for a reduced quantity of analgesic drugs to be used in the two experimental groups, the total amount and type of analgesic drugs received by patients were recorded on a daily basis from admission until discharge from intensive care. In order to measure the level of patients' pain it was necessary to develop a pain measuring instrument, to pilot the use of this tool and to implement it into every day use in intensive care. The pain-measuring tool was used to record the patient's level of pain before and after each massage only or aromatherapy massage and at corresponding times for patients in the control group.

To examine the study's third hypothesis and test whether it was possible for a reduced quantity of anaesthetic drugs to be used in the two experimental groups, the total amount and type of anaesthetic drugs received by patients was recorded on a daily basis from admission until discharge from intensive care. In order to measure the level of patients' sleep it was necessary to develop an instrument to do this, to pilot the use of this tool and to implement it into every day use in intensive care. The sedation-measuring tool was used to record the patients' level of sleep before and after each massage only or aromatherapy massage and at corresponding times for patients in the control group.

In order to address the study's fourth hypothesis and test whether the intervention had an effect on anxiety, depression and quality of life following discharge from intensive care, information was collected from patients at discharge and one month after discharge from intensive care, using two recognised measuring tools; the Hospital Anxiety and Depression scale (HAD, Zigmond and Snaith 1983), to measure anxiety and depression and the Short Form 36 questionnaire (SF-36, Ware and Sherbourne 1993), to measure quality of life. The patients completed the questionnaire at discharge from intensive care (in intensive care) before returning to the ward, whilst the second questionnaires, were either posted to the patients for completion or were posted to the ward in the hospital where the patient remained, one month later.

3.4. Study Design

A randomised controlled trial using a pre-test, post-test experimental design (Campbell and Stanley, 1963) was used for this study. This design uses a pre-test, randomisation of subjects to a control or experimental group, an intervention and a post-test (figure 1).

Figure 1. Pre test - Post test Experimental Design

R	O1		O2	Control Group
R	O3	X1	O4	Experimental Group 1
R	O5	X2	O6	Experimental Group 2

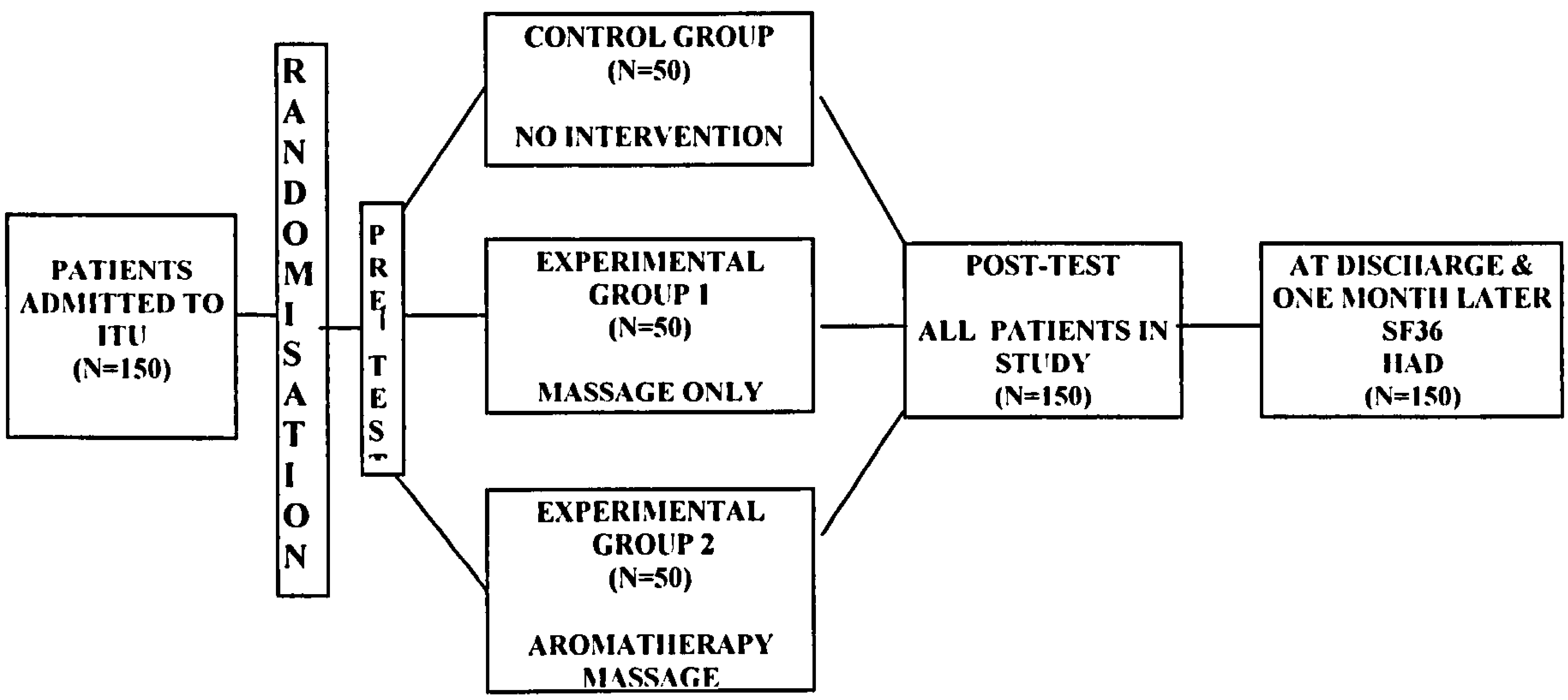
R = random allocation X1 = massage only

O = measurement X2 = aromatherapy massage

The purpose of the pre-test was to obtain a baseline record for all data collected as a measure of the effect of the intervention. It would also demonstrate that all three groups were comparable prior to the intervention. Randomisation ensured that all subjects had an equal chance of being allocated to either the control or experimental groups, and thus reduced the bias between groups. The intervention was then applied to the experimental groups. The post-test ensured that information relating to both the control and experimental groups was collected to enable comparisons to be made. The study design is illustrated in figure 2.

There have been few empirical studies that have examined the effects of massage only or aromatherapy massage in intensive care. The use of the above study design helped to demonstrate cause and effect by testing the hypotheses. The randomised controlled trial design was used to demonstrate acceptance or rejection of the hypotheses and control the validity and reliability of the study. This method was the most appropriate one to use because it allowed the systematic gathering of data, which can be used to identify general trends and rigorously test the hypotheses.

Figure 2. Study Design.



The rigorous testing of hypotheses is an area relating to the use of massage and aromatherapy massage which has been lacking but is required to substantiate the use of these therapies in nursing. It has become increasingly important to demonstrate the effectiveness of complementary therapies in a formalised manner (Anthony 1988). However, practitioners of complementary medicine have argued that the experimental approach is not the most appropriate methodology to use (Janine-Bell 1987, Aldridge 1989, McGortney and Hotchkiss 1993) due to it lacking the capacity to interpret individual effects, and is not therefore holistic in its approach (Watson 1991). It is also argued that under clinical conditions, complementary therapies are not practised in accordance with traditional requirements. However an experimental approach could demonstrate whether massage and aromatherapy were effective using a traditional methodology which was appropriate to intensive care and would have credibility in the medical environment. Also, intensive care is not necessarily an area where all traditional requirements for complementary therapies can be practised. Experimental methodology is the most powerful method for testing hypotheses of cause and effect relationships between variables and its strength lies in the confidence with which the causal relationships can be inferred. In complementary therapy nursing and many forms of orthodox medicine identifying a comparable manoeuvre against which to test an intervention is fraught with difficulty (Wall 1996). In this study the use of massage as well as aromatherapy massage helped to reduce some placebo effects.

3.4.1. Validity of the study design

The validity of the information collected (defined as the degree to which an instrument measures what it is intended to measure, Polit and Hungler 1989), was considered. The validity aimed to link concepts to observable facts. The internal validity and external validity were considered.

The overall design of the study was considered for its validity and suitability to the research application. It was selected as having acceptable validity, controlled for by the random allocation of patients to the experimental or control groups, and was feasible for the number of patients included, taking into consideration the researcher working alone within a limited time and limited geography.

3.4.1.1. External Validity

External validity was considered as 'the degree to which conclusions can be generalised' (Neale and Liebert 1986). There were three main areas of external validity that were considered.

Selection. This related to the selection of patients who took part in the study. Patients were randomly selected to ensure that an indiscriminate sample was achieved, and this helped to ensure that the findings of the study were generalisable to other intensive care units. The subjects in the study were a specific group, with few similarities, which could be generalised to other patient groups. The measures of pain, sedation, anxiety, depression and quality of life could be generalised to other similar areas such as theatres, recovery, accident and emergency where patients may exist with similar problems. The findings could be relevant to other intensive care units, but in the main it would be difficult to generalise this study to other clinical areas.

Setting. The area where the study was undertaken was very specialised and this has made it difficult to generalise the findings to other patient populations, except for those in intensive care.

History. The use of complementary therapies is a relatively new therapy, but with further conclusive studies and an increasing acceptance of new therapies it may be easier to implement them into the clinical area in the next century when they may not be classed as 'trendy' therapies.

3.4.1.2. Internal Validity

Internal validity was considered as 'the validity of empirical statements dealing with the question of whether X (as manipulated) caused a change in Y (as measured)' (Neale and Liebert 1986). Cook and Campbell (1979) suggested that there are many threats to internal validity and these have been considered in-turn.

History. This related to the specific events which occurred between the first and second measurement, in addition to the experimental variable. During the course of the study there were changes in patient admissions, with patients being more critically ill (demonstrated by an increase in the APACHE 11 score recorded on admission). This was due to an increased pressure to admit patients to intensive care (Bellis 1996) and limited staff being available. All three groups were subjected to the same changes and events.

Testing. This related to the effects of taking a test on the scores of a second testing. The effect of a second test cannot be measured in this study design. A Solomon Four-Group design (Campbell and Stanley 1967) would need to be used to measure the effect of testing. This study did not incorporate this design due to the limited number of subjects available and the time required.

Instrumentation. This related to changes in the calibration of the measuring instruments, or changes in the observers or scorers used in the study which could produce changes in the obtained measurements. All of the equipment used in intensive care is regularly checked and serviced. The equipment used to monitor patients in the study was calibrated at least three times a day to ensure that all clinical measurements remained consistent. There could have been some variations between the nurses recording information due to human differences, but random allocation and calibration of equipment ensured these effects were minimal. This helped to reduce the problem of instrumentation. Changes in staff occurred during the course of the study and new staff had to be trained during this time. This would not have affected data collection as all three patient groups would have experienced the same events. The reliability of both the pain and sedation scoring systems were measured and were found to demonstrate good inter-rater reliability.

Differences may have occurred when patients completed the questionnaires at discharge from intensive care, and one month after discharge from intensive care. At discharge the patient completed the questionnaire on the intensive care unit, but one month later the patient completed the questionnaire on his or her own, at home or on a hospital ward. This may have produced some differences in the measurements obtained. However, it would not have been viable to ask the patients to return to hospital to complete the questionnaires.

These three areas of internal validity were mainly controlled for in this study due to the study being experimental in nature, and subjects being randomly allocated to one of three groups.

Regression. This referred to patients being selected on the basis of their extreme scores. This did not occur in this study due to the use of inclusion and exclusion criteria, which excluded the most critically ill patients, and the random allocation of patients to one of three groups.

Mortality. This related to the loss of subjects from comparison groups due to their death. If patients died during the study the random allocation of patients to each study group would prevent any loss in the comparison groups.

These two parts of internal validity were controlled for in the experimental design by the use of a control group.

Selection. This may have been construed as a problem due to the large variation of patients available, but it was controlled for by using inclusion and exclusion criteria, and by random allocation of patients to each group.

Diffusion of treatments. This could have been a problem for patients in the control group as they were able to see other patients receiving a massage. However, this was not recognised as a problem as the curtains were drawn around patients' bed areas during a massage and therefore other patients could not see what was happening to the patient at that time. Patients were unable to speak to each other due to the presence of endotracheal tubes and were unable to mobilise further than their own bed area, due to the restricting equipment and the critical nature of their illnesses.

Compensatory equalisation of treatments. This was a similar problem to the diffusion of treatments. Patients or relatives could have asked to belong to the massage group and not be in the control group. This problem did not arise, as when consent was obtained it was made clear that there was an equal chance of being randomised to any group. None of the patients or relatives requested to be changed from their randomised study group.

Compensatory rivalry. This was not a problem during the study as patients were unaware of which study group other patients were allocated to due to them being too ill, being sedated and the use of curtains around the bed area to ensure privacy. A further consideration was the problem of researcher bias. The data were collected by nurses caring for the patient which may have been biased in itself. This was unlikely due to the critical nature of the patient's illnesses, the calibration of equipment, and a bedside computer recording information which made it difficult to bias any recordings as all patient information is collected electronically and can be checked.

3.5. Random allocation.

Patients were randomly allocated into three groups using a computer-generated table of numbers. Group one was the control group, group two was the massage only group and group three was the aromatherapy massage group. Patients were admitted to the intensive care unit and systematically reviewed for consideration to participate in the study. Once patients were screened using the inclusion and exclusion criteria, and consent had been obtained to be part of the study, then they were allocated to the next study grouping in the table of random numbers. In this study there were no deviations from random allocation and the data was analysed based on random allocation.

Even though random allocation of the sample to the study groups took place, the study was still subject to bias. Concerning random allocation, four main sources of systematic errors in trials of the effects of healthcare exist (Mulrow and Oxman 1997). These are selection bias, performance bias, attrition bias and detection bias. These four potential forms of bias affect different areas of a trial.

3.5.1. Selection bias.

One important bias that may have affected intervention comparisons is the way in which the groups being compared were assembled (Kleijnen et al 1997). It is important that the researcher should be unaware of the order of the study groups until after the subjects have been recruited i.e. the researcher should be unaware as to which group the subjects would be allocated to, until after they have been recruited into the trial. In order to achieve this, someone who would not be recruiting subjects into the trial should generate the randomisation details. This method of controlling for selection bias is referred to as allocation concealment (Mulrow and Oxman 1997). Allocation concealment is thought to be more important in preventing bias than other components of allocation such as the generation of the randomisation. Schulz et al (1995) and Chalmers et al (1989) have shown that a lack of adequate allocation concealment is associated with bias.

In this study, having pre-numbered data collection files which were administered serially to the subjects recruited into the trial, adhered to allocation concealment. A table of random numbers was computer generated by a statistician for 150 subjects which were divided into three groups. The person recruiting the patient kept all data collection files away from the patients in another room until after recruitment to prevent any selection bias. This was so that they did not know which group the patient would be allocated to, thus preventing bias.

Another type of selection bias is referred to as reserve blinding (Mulrow and Oxman 1997). This referred to the blinding of treatment groups after allocation to the groups had occurred, and prevented the data collector knowing which group the subject had been allocated to until after all the data had been collected and the codes were revealed. In this study it was not possible to adhere to reserve blinding due to the subjects receiving massages in the experimental groups, making it obvious which groups subjects belonged to.

3.5.2. Performance bias.

'Performance bias refers to systematic differences in care provided to comparison groups other than the intervention of interest' (Mulrow and Oxman 1997: 36). Some research (Colditz et al 1989, Karlowski et al 1975) suggested that those providing the care should be 'blinded', so that they do not know which study group the subject has been allocated to. Other research (Sackett 1979, The Canadian Co-operative Study Group 1978) has shown that contamination (provision of the intervention to the control group) and co-intervention (provision of unintended additional care to either comparison group) can affect study results. A further problem, which was reported by Karlowski (1975) is that those subjects who are aware of their study group report more symptoms leading to biased results.

In this study it was difficult to control for performance bias. Some of those providing care and some of the subjects in the study were aware of the study group to which they had been allocated. This was dependant on whether subjects were awake or asleep and therefore they could observe and feel the massages. Some nurses may have been aware of the study groups if they were present during the massage (for example if they were caring for that patient when the massage was performed).

3.5.3. Attrition bias.

Attrition bias refers to systematic differences between groups in loss of participants from the study and is sometimes referred to as exclusion bias (Mulrow and Oxman 1997). Loss of subjects from the study, such as withdrawals, dropouts or protocol deviations should all be accounted for as these subjects have great potential for biasing the results. All participants who were 'lost' from the study have been accounted for in detail in the data analysis and no differences were found (pgs 215-231).

3.5.4. Detection bias.

Detection bias refers to systematic differences in outcome assessment (Mulrow and Oxman 1997). Detection bias can also occur due to selective reporting of results. It is important to obtain missing data to prevent or reduce the effects of this bias. All efforts were made during the study to obtain as much data as possible to reduce the amount of missing data. Reference has been made to all missing data so as not to bias the results.

3.6. Population and Sample

Access to the intensive care unit (ICU) was gained by verbal agreement prior to commencement of the study from the Clinical Director and the Directorate Manager of the unit. The potential population comprised all patients admitted to the ICU at a large teaching hospital in Liverpool, during the period of August 1994 to December 1997.

3.6.1. Characteristics of the ITU Setting

The study ICU was a busy unit with a maximum of thirteen beds. During the study period bed occupation was increased from accommodating a maximum of ten patients to a maximum of thirteen patients. The unit admitted both medical and surgical patients who were critically ill from within the Mersey Region. The unit was an adult ICU and therefore admitted patients over the age of sixteen. The hospital acted as the regional renal catchment hospital which meant that patients requiring haemodialysis, haemofilitration or plasma exchange as well as ventilation were also treated there. Some patients who required dialysis may be transferred from other hospitals within the region. Patients can be transferred long distances to an ICU bed depending on the local and regional ICU bed availability (Mason 1995, McNicholas 1995, Bellis 1996, Dickson 1996).

3.6.2. Patients

The majority of patients admitted to the ICU were critically ill and the mortality rate for 1994 was 26% (n=125), of all admissions (n=480), and for those patients who stayed longer than three days, the mortality rate was to 20% (n=96). In 1995 there were 489 admissions to ICU and the mortality rate was 33% (n=162). The mortality rate was 18% (n=90) for those patients who stayed longer than three days in ICU. In 1996 there were 451 admissions to ICU and the mortality rate was 35% (n=160). The mortality rate was 22% (n=101) for those patients who remained in ICU longer than three days. In 1997 there were 680 admissions, and the mortality rate was 28% (n=190). The mortality rate was 14% (98) for those patients who remained in ICU longer than three days. Table 3.1.

Table 3.1. Patient admissions in ICU from 1994 to 1997

YEAR	1994	1995	1996	1997
No. of admissions	480	489	451	680
Total no. of deaths	125 (26%)	162 (33%)	160 (35%)	190 (28%)
No. of patients in ICU after 3 days	216 (45%)	218 (43%)	229 (51%)	277 (41%)
No. of deaths after 3 days in ICU	96 (20%)	90 (18%)	101 (22%)	98 (14%)
Mean APACHE 11	21	21	21	20

The characteristics of the patient population did not change over the study period, demonstrated by no change in the mean APACHE II score from 21 in 1994, 1995 and 1996 and 20 1997. Table 3.1. There was a merger of two ICUs, to form one ICU at the Royal Liverpool University Hospital. This initially led to a loss of two ICU beds and only the most critically ill patients could be admitted. During data collection there was also a lack of regional ICU beds (Mason 1995, Bellis 1996), which meant that the more acute critically ill patients could be admitted. Many of these patients did not fulfil the inclusion and exclusion criteria for this study, which affected patient recruitment into the study by slowing down the recruitment rate. However this is not demonstrated by changes in patient figures from 1994-1997. (Table 3.1)

3.6.3. Nursing Staff

At the time of the study the ICU underwent a major merger with another ICU which consequently led to staff from both units working together in one environment. This resulted in many changes to ensure that clinical practices were the same. The merger culminated in a total of 91 nursing staff ranging from auxiliary staff to senior sisters. There was one H grade post, which was the ICU nurse manager. Twenty-one (23%)

of the nurses were sisters, eleven (13%) were grade F (junior level), and ten (10%) were grade G (senior level). Forty six (51%) of the nurses were senior staff nurses at grade E, and seventeen (18%) were grade D (junior staff nurses). Seven (8%) of the staff worked as auxiliary nurses who were available to assist in the delivery of nursing care. Nineteen (20%) of the staff worked on a part time basis. There were a total of nine (9%) male nurses. The English National Board, Intensive Care Nursing (ENB 100) course was being run at the time of the study and post registration students were also on the unit undertaking the practical component of the course. This also applied to pre registration student nurses and other post registration nurses who were undertaking courses (theatre nurse course, renal course etc.). This did not mean that the staffing levels were improved at this time, as the students were supernumerary and were paired off with a trained member of staff for the duration of their shift. The trained nursing staff often had the dual responsibility of caring for the patient and teaching an undergraduate or post-graduate student, thus increasing their workload.

3.7. Inclusion and Exclusion Criteria

A list of inclusion and exclusion criteria was developed as part of the study to enable patient selection to be consistent.

3.7.1. Inclusion Criteria

It was felt that all patients admitted to the intensive care unit were potential subjects to enter the study, and only those fulfilling the exclusion criteria were not recruited.

3.7.2. Exclusion Criteria

Patients fulfilling the following criteria were excluded from the study.

1. Patients who had a positive skin patch test. This involved applying a few drops

of 2.5% bergamot oil to a small area of skin at the top of the thigh, and observing for any allergic reaction. If any redness or irritation occurred within a twelve hour period then this indicated a positive skin patch test, and the patient was eliminated from the study.

2. Patients who were brain dead on admission and therefore fulfilled brain death criteria.
3. Patients who did not wish to take part in the study, or whose relatives did not consent on behalf of the patient.
4. Patients who were admitted for an overnight stay, or whose stay was less than three days.
5. Patients who were known to have any psychological aversions to being touched or handled.
6. Patients who had any contagious or infectious skin conditions.

3.8. Patient Recruitment

Patients who fulfilled the inclusion and exclusion criteria were recruited into the study. The study was explained in detail to the patient (if they were awake) or to the next of kin and a patient information sheet was given to them to read (appendix 1). Consent to take part in the study was obtained by the researcher, and any of the nurses trained in the massage procedure, who could explain the study in detail. The patient and relatives were allowed time to read the information sheet so that they could make an informed decision regarding participation in the study. Patients were recruited into the study by gaining written consent (if possible) or verbal consent from the patient, or by written consent from the next of kin. The consent was obtained by completion of the consent form (appendix 2).

3.8.1. Informed Consent

Informed consent is difficult to obtain from patients in intensive care as they are usually admitted to intensive care without prior indication and their illness is usually so severe that they are sedated and ventilated. They are therefore unable to consent to take part in a research study. In these cases the next of kin was asked to consent on behalf of the patient. The ethical problems of approaching relatives who were distressed and vulnerable was difficult, and some relatives found it hard to consent for entry into the study. It was acknowledged that this was not true informed consent for the patient and was partly overcome by explaining the study to the patient once they were awake and well enough to comprehend the details. The right to withdraw from the study at any time was again reiterated to the patients at this point.

Some other problems arose during patient recruitment. A fairly large proportion of patients (n=1285, 61%) were excluded from the study over the data collection period due to the shortness of their stay i.e. less than 3 days (n=1176, 56%), due to their legs not being accessible for massage (n=81, 4%), some patients disliked being touched (n=9, 1%) and in some cases it was impossible to obtain consent (n=19, 1%). Table 3.2. A further problem arose mainly relating to those patients who remained on ICU for a period of time greater then two weeks. These patients or their relatives began to ask if they could receive a leg massage because they were feeling uncomfortable. In these cases the study protocol was explained again, and patients were removed from the study if requested. No patients asked to be taken out of the study so that they could receive a massage.

Table 3.2. Numbers of patients omitted from study 1994-1997

Reason Omitted from Trial	Number of Patients				
	1994	1995	1996	1997	Total
Shortness of Stay (i.e. less than 3 days)	264	287	222	403	1176
Legs Inaccessible	15	26	22	18	81
Disliked being touched	1	3	3	2	9
Unable to obtain Consent	5	5	6	3	19
Total	285	321	253	426	

3.9. Methods of data collection

Once informed consent had been obtained patients were randomly allocated to one of three groups.

GROUP	INTERVENTION
control	no massage or aromatherapy massage
experimental 1	leg massage for 20 minutes using almond oil
experimental 2	leg massage for 20 minutes using 2.5% bergamot essential oil in almond oil

On admission detailed patient data were collected including age, sex, current employment, diagnosis, APACHE 11 and patient life events. This information was recorded from patient records or the patient (if possible), but otherwise it was obtained from the next of kin. The amount and type of anaesthetic drugs and analgesic drugs given to each patient was recorded on admission and on each consecutive day of the patient's stay. The TISS (therapeutic intervention scoring system) score was also recorded daily. On the day following admission, patients in the study received the applicable intervention. Those in experimental group one received a leg massage with almond oil lasting for 20 minutes on day two, and for every third day of their stay. Those in experimental group 2 received a leg massage with 2.5% bergamot oil lasting for 20 minutes on day two, and for every third day of their stay. All massages lasted for 20 minutes and followed a set protocol (appendix 3). The patients in experimental group two received a skin patch test to assess their sensitivity to bergamot oil prior to the massage (appendix 4). The first massage was given the day after admission, to allow time for medical and nursing procedures to be undertaken, such as the insertion of lines for monitoring, intubation and attachment to a ventilator, and the setting up of equipment. This also allowed time for the next of kin to adjust to their relative being admitted to ICU, enabling them to make a rational and informed decision to consent to their relative taking part in the study.

Patients continued to receive massages every third day they were on the ICU until discharge to the ward or they died. It was not possible to continue with the study intervention post discharge from ICU because of the problem of gaining consent to massage patients who were under the care of other consultants in other directorates within the same hospital.

Immediately pre and post intervention, and one and four hours post intervention, physiological recordings of blood pressure (systolic, mean and diastolic), heart rate, respiratory rate, sedation score and pain score were taken. At the time of discharge from ICU patients were asked to complete two questionnaires (HAD, Zigmond and Snaith 1983 and the SF36, Ware and Sherbourne 1993). The same two questionnaires were sent to the patient's one calendar month following discharge from ICU for them to complete. See timetable for data collection, table 3.3.

Table 3.3. Data Collection Schedule.

TIME	DETAILS COLLECTED				
On Admission	Age, sex, current employment, diagnosis, APACHE 11, life events, amount and type of hypnotic drugs, amount and type of analgesic drugs, sensitivity to bergamot oil (if in group 3)				
Daily	TISS, bed position, amount of time relatives visited, amount and type of analgesic drugs, amount and type of hypnotic drugs				
		time point 1-1400 hrs	20 minutes later	one hour later	four hours later
2nd day and then every 3rd day	Massage if in groups 2 & 3	HR SBP DBP RR sedation score, pain score	HR SBP DBP RR sedation score, pain score	HR SBP DBP RR sedation score, pain score	HR SBP DBP RR sedation score, pain score
At Discharge	HAD SF 36				
One Month Post Discharge	HAD SF 36				

Key.

HR heart rate
SBP systolic blood pressure
DBP diastolic blood pressure
RR respiratory rate
SF 36 Short form 36 (Ware and Sherbourne 1992)
HAD Hospital Anxiety and Depression Scale (Zigmond and Snaith 1983)

3.9.1. Study Intervention

The massage procedure used in this study involved a 20 minute massage to the legs of the patient, using either ten millilitres of almond oil (experimental group 1), or ten millilitres of almond oil with an additional five drops of bergamot essential oil (experimental group 2). The oil was equally distributed between both legs. The legs were utilised, as these were the most accessible area of the study population as they were least likely to have lines inserted into them and they had a relatively large surface area for the absorption of the oil. This did reduce patient entry to the trial, as patients who had suffered leg amputation or who were involved in an accident requiring traction, pin insertion or plaster of Paris to the leg/legs were unable to be admitted into the study due to the legs being inaccessible. There is literature to suggest that the legs of patients in ICU should not be massaged because of the risk of mobilising a deep vein thrombosis, which could lead to death (Price 1993). This point was considered and it was decided that only light and gentle massage movements such as efflurage would be used and that a large part of the massage involved the feet, thus reducing the risk of mobilising a thrombus. Patients were continually monitored for the risk of thrombosis and all patients in ICU routinely received prophylactic mini-heparin to reduce this risk (unless otherwise indicated). Patients were also closely monitored so that any problems would be immediately noticed, and in these cases a massage was not administered. At each massage time point, two nurses assessed the suitability of patients to receive a massage independently using the intervention exclusion criteria (pg167). The legs were not washed for 24 hours following the massage so that the oils had time to absorb into the skin.

The massages were performed at approximately the same time on each occasion. It was decided that 1400 hours would be the most appropriate time to undertake the massages, as this was the hand-over period for the nurses and therefore more nurses were available at this time. This did not interfere with patient visiting times as the unit practised open visiting and relatives were able to visit at any time. If relatives were present they either sat quietly at the bedside, or went outside the unit whilst the massage took place. The nurse caring for the patient collected the appropriate data.

It was not always possible to undertake the massages at 1400 hours usually due to the patient having a scan or undergoing a procedure in the operating theatre. The massage was then carried out as soon as possible on that day or if this was not possible the massage was omitted.

3.9.2. Massage Procedure

A group of six nurses who had undertaken a short eighteen week course in massage and aromatherapy (ENB N17, Aspects of Therapeutic Nursing) were recruited to perform the massage procedure. A standard protocol for the massage technique and massage timing was developed (appendix 3). The six nurses all received training in the massage technique and duration of movements.

An agreed protocol of the massage technique and time taken for each movement was used throughout the study and was available in each of the patients data collection schedules for the nurses to follow. This was to reduce differences in the massage technique and time taken.

A small sub study was undertaken to determine the reliability of the time taken by each of the nurses to massage patient's legs and to determine the reliability of each of the nurses massage technique. Each nurse was timed on three occasions undertaking a massage procedure. The mean time for each nurse to undertake the massage procedure on one leg was between 6.9 minutes and 8.1 minutes. The protocol time was ten minutes. Table 3.4. This meant that each nurse took less than the agreed time to undertake the massages, but all the nurses took approximately the same time to undertake the massages and all adhered strictly to the procedure by following the exact massage procedure. The small standard deviations show that each nurse was fairly consistent in the time taken for each massage. Statistical testing using Kruskall-Wallis found no significant difference between the nurses massage times, showing that they all took a similar length of time to follow the massage protocol. Nurses used the massage protocol (appendix 3) at the patients' bedside whilst undertaking the massages to ensure that all procedures were as similar as possible.

Table 3.4. Mean times taken to follow massage protocol

	Nurse 1	Nurse 2	Nurse 3	Nurse 4	Nurse 5	Nurse 6
Mean time (minutes)	7.6	6.9	7.1	7.2	8.1	7
Range (minutes)	7.18-8.03	7.38-6.42	6.85-7.28	7.15-7.2	7.2-8.93	7.53-6.48
Standard deviation	0.6	0.68	0.3	3.5	1.2	0.74

3.9.2.1. Sensitivity to Bergamot Essential Oil

All patients randomly allocated to experimental group B were skin patch tested for sensitivity to bergamot oil (see appendix 4 for details of patient skin patch testing). No patients were found to be sensitive to the oil. In some cases bergamot oil can cause photosensitivity when exposed to sunlight. The bergamot oil used in this study was bergaptene free (the part of the oil to cause photosensitivity) and was not thought to cause problems with photosensitivity when exposed to sunlight (Watts 1992). Also, patients within the intensive care are not exposed to sunlight.

3.10. Instrument Selection and Design

All the instruments selected for data collection were subjected to rigorous examination regarding their reliability, validity and standardisation.

The reliability of the information collected, defined as the degree of consistency or accuracy with which an instrument measures the attribute it is designed to measure, (Polit and Hungler 1989), was considered. It was acknowledged that the recording of observed care might be liable to researcher bias. In order to strengthen the reliability of the study inter-observer checks were conducted throughout the study using the following measures, the modified New Sheffield Sedation Scale, the six-point pain scale, the massage procedure (time taken and technique used).

The validity of the instruments selected was examined to determine if the scale was measuring what we thought it was (Streiner and Norman 1992). There are many different ways of addressing validity but Streiner and Norman (1992) use three main headings under which to discuss validity which all address the same issue of 'the degree of confidence we can place in the inferences we draw from scores on scales'.

<u>Construct Validity;</u> Construct validity is the ability to generalise concepts or mini-theories which explain the relationships among various behaviours or attitudes, for example, life satisfaction, quality of life, pain or depression (Sreiner and Norman 1992) Construct validity aims to measure the relationship between the hypothetical construct and the instrument. Most psychological measures of health are designed to tap some aspect of a hypothetical construct. Construct validity within this study

relates to the measurement of pain, sedation, anxiety, depression and quality of life (see pilot study, appendix 7).

Criterion Validity; Criterion validity is the correlation of a scale with another measure of the item under study, ideally a "gold standard", which has been used and accepted in the field. (Streiner and Norman 1992) Criterion validity can be divided into two types, which are differentiated by the difference in the timing of obtaining measurements on a criterion;

concurrent validity - the new scale is correlated with the criterion measure (gold standard measure), at the same point in time.

predictive validity - the criterion will not be available until some time in the future, due to the nature of the item being measured. It refers to the adequacy of an instrument in differentiating between the performance or behaviours of subjects on some future criterion.

Content Validity; Content validity or face validity is concerned with the sampling adequacy of the content area being measured, for example is the measure wide enough to cover a spectrum of events and specific enough to categorise these events. (Streiner and Norman 1992)

The standardisation of the measure is the ability to make comparisons with other people measured on the same scale (Coolican 1999). The process of standardising however involves adjusting it until it is a useful measure of the population it is targeted at and will enable comparisons of individuals with confidence. This involves testing large samples of the population to determine means and standard deviations.

It was outside the realms of this thesis to undertake standardisation of the new measures used in this study but further research would help to standardise the measures used.

The following section discusses each method of data collection or instrument used for data collection.

3.10.1. Demographic Data

On admission to the study, detailed patient demographic datum was recorded including age, sex, diagnosis and current employment (to determine social class identified by the Registrar Generals Classification 1995) to provide a profile of the sample and to determine any differences between patient groups. This information was obtained between 1994 and 1997 from examining the patient records and by asking the patient (if able) or by asking the next of kin. This information was collected so that patient groups within the study could be identified in order to make comparisons with other patient groups and to ensure that there was equal representation throughout the three study groups (control, experimental 1, experimental 2)

3.10.2. APACHE 11

APACHE 11 scores (Knaus et al 1985) were recorded to quantitatively determine the severity of patients' illness on admission to intensive care. The APACHE 11 score is a physiological scoring system, which was originally designed to predict ICU patient mortality (Knaus et al 1985). It was developed to enable standardisation of patients admitted and treated, describe accurately and classify groups of patients on the severity of their illness, and to allow assessment of new therapies. The score is determined by surveying the first 24 hours of the patients' admission. The scoring system was developed using a variation of the nominal group process in which a panel of experts selected clinical variables and assigned weights to them. Twelve routine physiological measurements are scored, receiving a score of nought if they are within the normal range, and up to a maximum score of four if grossly abnormal. The maximum APACHE 11 score is 71. The system comprises of two parts, a physiology score representing the degree of illness, and a pre admission health evaluation determining any pre existing chronic illness and can be used to obtain a prediction of mortality.

It was originally validated on 5815 North American ICU patients in 13 units and when the patient predicted risk of mortality was compared to actual mortality figures to obtain the goodness of fit, the score gave a correct classification rate of 86% (Knaus et al 1985). A large validation study of the APACHE 11 in Britain was undertaken in 1993 which showed good agreement with the original North American study (Rowan 1993). The study examined 8796 admissions in 26 units throughout Britain and Ireland. The only area where the agreement was not as good was with very elderly patients, aged 80 years or more. In Britain the actual death rate is higher than would be predicted using the APACHE 11, although the reasons for this are not clear. The study did show that ICU patients in Britain are considerably sicker on average than those in the North American validation study.

The APACHE 11 score was already in use within the ICU and as discussed in the literature has acceptable levels of reliability and validity. It is also widely used in other ICU's and therefore comparison between patients studied in other ICU's can be determined.

3.10.3. Social Readjustment Rating Scale

A list of patient life events were gathered by patients' recollecting which events had happened to them in the previous year using the social readjustment rating scale (Holmes and Rahe 1967). If the patient was unable to do this, the next of kin was asked to recall the information behalf of the patient. The information was collected to determine any differences in stress (measured using life events) between patients. This was an attempt to obtain a baseline measure of stress for patients on admission to ICU which may have an effect on the psychological variables of depression and anxiety, measured using the hospital anxiety and depression scale (Zigmond and Snaith 1983) and the eight domains of quality of life, measured by the short form 36 questionnaire (Ware and Sherbourne 1992).

The social readjustment rating scale was developed to measure those social events which require life adjustment and are significant to illness onset. The scale consists of a checklist of 43 events (empirically derived from clinical experience), from which patients can indicate which if any of the events have happened to them in the past year. Each event is assigned a weighting which reflects the degree of disruption that would be caused should that event befall an average person. An individuals' score is the sum of the events he/she reports.

The scores were developed by using a convenience sample of 394 subjects who rated the 43 events. Marriage was given a figure of 50 as a mid reference point and other events were scored between 0 and 100 depending on the amount of turmoil, upheaval and social readjustment which was required. The resulting scores ranged from 11 (minor violations of the law), to 100 (death of a spouse). High consensus concerning the relative order and magnitudes of the life events (r = >0.90) was demonstrated using Pearsons correlation coefficient (Holmes and Rahe 1967) and in further work the instrument was shown to be reasonably reliable (Casey et al 1967)

3.10.4. Therapeutic Intervention Scoring System

The Therapeutic Intervention Scoring System (TISS), is a quantitative method used to compare the number of patient interventions in a 24 hour period, by the addition of 57 items of work (Keene and Cullen 1983). It is often used in intensive care to measure workload (Malstam and Lind 1992). It was selected for use in this study to measure how busy patients were in order to gauge how critically ill they were on a daily basis. A committee of intensive care physicians and nurses assigned respective point values to the various interventions according to the time and effort required for nursing care. The 57 items of work were scored from one to four according to the intensity of involvement. Interventions given four points would only be considered in patients who were exceedingly ill. An experienced observer such as an ICU nurse summates the points per patient per 24 hours, and patients are classified into four categories (1 - 1V), in order to simplify and organise activities relating to patient care. Guidelines were provided for the use of TISS in the reference manual (appendix 9) Patients were classified depending on their TISS score, with more points indicating an increased workload;

class 1V	> 40 points
class 111	20 - 39 points
class 11	10 - 19 points

class 1 < 10 points

TISS was originally developed to allow quantitative comparisons of patient care between intensive care units. It was developed in South America in 1974 (Cullen et al 1974), and it was updated in 1983 to accommodate more recent innovations in critical care. Reliability tests undertaken in 1974 against independent clinical estimates of the severity of illness in 850 patient days demonstrated that 96% of patients of general wards were not critically ill (TISS<2.2 per patient), whilst 90-100% of patients in ICU were properly utilising ICU beds (TISS=7.7-31.8 per patient). Keene and Cullen (1983), demonstrated the 1983 system was equivalent to the 1974 system in 100 patients in three units, using a regression equation (y=0.5+1.03x). They also demonstrated that the separation of points between four categories (1-1V) suggested that clinical classification of patients into the four groups was valid and consistent.

The TISS scoring system was chosen from a selection of scoring systems (Dannert et al 1975, Greenberg et al 1978, Slatyer et al 1986, Miranda et al 1990, Hjortso et al 1992), due to its ease of use and it has acceptable levels of reliability and validity. It only takes a couple of minutes each day to assign interventions and tally up points to determine the TISS score.

3.10.5. The New Sheffield Sedation Scale

The New Sheffield Sedation Scale was developed in 1992 (Laing 1992) due to deficiencies in previous scales. Existing scales were mainly developed to test the use of new sedative drugs (Ramsay 1974, Cook and Palma 1989) and were crude in their application to patient care. The new Sheffield sedation scale was developed by a nurse for monitoring the sedation of patients in intensive care. It was designed to measure whether optimum sedation levels in ICU patients were achieved. The scale was easy to understand with a simple description of each level of sedation allowing the measurement of sedation to be straight forward and understandable. The scale consisted of a six point numerical scoring system ranging from level one (fully awake) to level six (completely unresponsive) and incorporated detailed explanations of each level which were easily understood and easily applied to ICU patients. It was simple, self explanatory and easily understood by new and experienced staff.

No work has been undertaken regarding the reliability of this tool, except for a two week assessment of its ease of use which was employed and involved nurses completing a questionnaire. This demonstrated that the scale was easily understood, practical, straightforward and that patients were kept at optimum sedation levels (as assessed by the nurse) (Laing 1992).

The new Sheffield sedation scale was chosen for use in this study to monitor the effects of the intervention on patients' sedation levels and patient comfort related to a decrease in hypnotic drugs and the study intervention. It was easy to use, self-explanatory and the levels of sedation were fully explained, however it was developed slightly for use in this study. The scale did not incorporate the measurement of paralysis or sleep and these variables were therefore incorporated into the modified scale prior to the scale being introduced for use in the study (appendix 5).

Reliability testing of the modified instrument used to measure sedation was employed as part of the study. Patient sedation scores were recorded during the data collection period to determine the reliability of the instrument. The Kappa coefficient was calculated as a measurement of agreement (K=0.73, demonstrating a good agreement). The Kappa coefficient is an agreement statistic (Cohen 1960). Cross tabulation of the sedation scores between two nurses also demonstrated a good correlation. The modified scale was shown to have an excellent reliability (Olleveant et al 1998).

3.10.6. Six Point Pain Scale (a semantic differential).

It is difficult to assess pain in ICU, due to patients being sedated and having an endotracheal tube through their vocal cords preventing them from speaking. Pain assessment is important in this study to determine the effects of bergamot oil on pain levels. No recognised scoring systems were available for use in ICU to assess and monitor pain and therefore a pain scale was devised for use in this study. In the study the massages were not necessarily performed when the patient had pain. All the massages were performed at the same point in time in the day.

A six point pain scale was developed using the paediatric pain scale of faces (Bieri et al 1990). The faces ranged from showing no pain (score 1) to extremely painful expressions (score 6), (appendix 6). A facial grimacing analysis scale had been developed by psychologists (Tyler et al 1993), but this was thought to be inappropriate to use in this study as it would involve intense training of all the staff and the reliability of the scale would need to be determined. Little reliability testing has been undertaken on the paediatric pain scales. Therefore a small study was undertaken to determine the reliability of the scale introduced to the ICU. Inter-observer checks were performed on 35 occasions between two nurses and one patient. The nurses and patients varied during the checks. The Kappa coefficient was calculated, K=0.7 (n=35) between the two nurses and between the nurse and the patient. The Kappa coefficient is an agreement statistic (Cohen 1960). The pain scale developed for use within this study was shown to have a good reliability.

3.10.7. Physiological Parameters

Physiological parameters of heart rate, systolic blood pressure, diastolic blood pressure and respiratory rate were recorded as an indication of how relaxed and comfortable patients were. These parameters can be used as indicators of pain and distress (Sutcliffe 1993). A decrease in any of these parameters could suggest that the patient had reduced pain or felt more relaxed and comfortable. However, these parameters may be difficult to assess due to the unstable nature of some patients in ICU, also the patients are on ventilators to assist their breathing most of the time therefore preventing the patient from breathing for themselves and for the respiratory rate to change. Previous studies have demonstrated little difference in the parameters of blood pressure and heart rate (Stevenson 1992, Buckle 1993, Dunn et al 1995). The instruments used to measure systolic and diastolic blood pressure were arterial lines attached to a monitor via a pressure monitoring kit. Hewlett Packard manufactured the monitors in use at the time and Baxter manufactured the pressure monitoring kits. These were chosen as the method of measuring blood pressure because they were already in use in the ICU and all members of staff were able to measure blood pressure in this manner. The monitors also accurately measure physiological parameters. The heart rate was also measured using the monitors.

Gassert (1990) argued that if an instrument is developed to measure the physiological parameter for which it was developed its validity is constant, and that the reliability of a physiological instrument is evident in its sensitivity, stability and precision. Murdaugh (1986) defined sensitivity as the ability of the instrument to detect small changes in the variables being measured, stability as the ability of the instrument to maintain accuracy of a given time after calibration, and precision as the exactness accuracy of results.

The sensitivity of the transducers (within the pressure monitoring kits) is demonstrated by the measurement of systolic and diastolic arterial blood pressure in one mmHg increments and heart rate in increments of one beat per minute. Stability and precision were maintained by undertaking regular recalibration to zero pressure. Precision of accuracy is maintained by regular maintenance of monitors and by changing the transducers every three days or sooner if there appears to be a problem.

Respiration were measured by the artificial ventilator being used by the patient or by the monitor via the ECG leads and displayed on the monitor, or by observing the patient chest movements, and counting the respirations.

The physiological parameters were measured by the nurse caring for the patient, the recordings were read from a monitor and therefore should not suffer from bias, due to the nurses mechanically taking the measurements. All the measuring equipment used in the ITU is also subjected to calibration at least three times a day and whenever the patient is moved to ensure the accuracy of the readings. This again helped to reduce any bias. The nurse would also not have known which study group the patient was in, due to the coding on the front of their data collection schedule.

It was decided to measure these parameters in this study to compare data with previous studies, and because the data is readily available. It was felt that a change of 10mmhg to be a significant change in blood pressure, and a change of ten beats per minute to be significant for heart rate. A change of five in the respiratory rate was thought to be a clinically significant change.

3.10.8. The Hospital Anxiety and Depression Scale (HAD)

To investigate the variables regarding depression and anxiety it was decided to use the HAD scale (Zigmond and Snaith 1983). The variable of depression was measured to determine any effects Bergamot oil may have induced, as this is one area where there is no anecdotal or empirical literature of its effects, only book references (Price 1995, Tiran 1996). The HAD was chosen as patients needed to complete a questionnaire with as much ease and speed as possible. The HAD is a short questionnaire and it was felt that this was most appropriate for critically ill patients who may have a short attention span and be feeling unwell. It has fourteen questions and gives separate scores for both anxiety and depression (Zigmond and Snaith 1983). It was specifically designed to exclude any physical symptoms of anxiety or depression as it was originally used with medical or surgical outpatients, where the physical symptoms of their illness could mimic anxiety. This exclusion of any physical symptoms of anxiety allowed the separate testing of physical manifestations. When validated against two other questionnaires widely used to assess depression and anxiety, namely the Irritability Depression and Anxiety scale and the subscales of the General Health Questionnaire, the HAD showed a slight advantage. It was also found to give a very low percentage of misclassifications of respondents (Aylard 1987). For the anxiety sub scale Zigmond and Snaith (1983) found 5% false positives and 1% false negatives. A score of 7 or less for anxiety or depression can be taken as a non-case, 8-10 for either subcategory as doubtful cases and scores of 11 or more as definite cases of severe anxiety or depression. The internal consistency of the two sub scales has been tested by looking at the correlation between each item and the sub scale score, for anxiety the correlation's ranged between 0.76 to 0.41, $p<0.01$ and for depression 0.6 to 0.3, $p<0.02$. The HAD questionnaire is particularly useful with ICU patients not only because it is short, but also because it contains easily understood, concise questions.

3.10.9. The Short Form 36 (SF36)

The short form 36 (Ware and Sherbourne 1992) was developed in the USA to measure patients' quality of life. It was developed from two larger surveys, which were used to define health status; The Health Insurance Experiment (Brook et al 1983, Valdez et al 1989, Ware et al 1986) and The Medical Outcomes Study (Anderson et al 1990) and both these surveys were used to produce a short generic measure of subjective health status. There are 36 items, which are divided into eight dimensions. Scores are obtained by summing item responses and with the use of a scoring algorithm they are transformed into a scale from 0 (poor health) to 100 (good health). There is also a single item giving information on change in health over the past year.

The SF36 (Ware and Sherbourne 1992) was chosen for use in this study as it is the shortest generic measure in regular use and the most comprehensive. It is simple and easy to complete, only taking respondents five to ten minutes, which is important for ICU patients who are recovering from a critical illness and have limited concentration spans. Also studies demonstrate that the response rate in postal surveys is good (Brazier et al 1992, Jenkinson et al 1993), and this was important as the questionnaire was posted one month after discharge from ICU, if the patients had been discharged home.

The version of the SF36 used in this study was the SF36 UK version, which has some minor modifications to six items to make it acceptable for use in the UK (Ware 1993). The SF36 has been used in two major studies in the UK (Brazier et al 1992, Jenkinson et al 1993), which have demonstrated high levels of internal reliability. The SF36 has demonstrated an ability to detect large effects (McHorney et al 1993), but further research is needed to determine smaller differences.

Brazier et al (1992) demonstrated in their study that the construct validity of the questionnaire is good allowing it to make distinctions between different population groups. This makes it valuable for use in ICU where limited outcome measures have been used, especially in relation to quality of life. Delamothe (1994) argued that it is important to include some measure of quality of life and patients perceptions in randomised controlled trials to assess the impact of health care.

3.11. Pilot Study and Instrument Development

The methods, instruments developed and feasibility of data collection were tested in a pilot study undertaken between December 1993 and January 1994 (appendix 7).

A small study was set up to test the validity of the newly developed pain and sedation scales, which demonstrated that both of the scales appeared to be measuring pain or sedation. Although further work is required and should be ongoing to establish the construct validity of these two scales. These small studies demonstrate that both the constructs of pain and sedation were being measured and both scales demonstrated good reliability (Olleveant et al 1998).

Amendments to the data collection schedule were made on completion of the pilot study. All terms used in recording the information were defined and clarified during the development of the schedule, which was made available to all ICU staff in the form of a reference manual during the main study. All information collected was coded.

3.11.1. Revision of Methods of Data Collection

On the basis of the pilot study, the following revisions were made for the main study:-

- Patients as well as the next of kin were asked to complete a list of life events about the patient. If the patient was unable to complete this list on admission they were asked to complete it when they are able.
- The GHQ 12 was excluded from use in the main study due to patients finding the

number of questionnaires for completion overwhelming and some patients not completing all the questions. A further factor which contributed to this decision was that the GHQ 12 recorded higher scores demonstrating a ceiling effect and it appeared that the HAD was more sensitive for this group of patients. The GHQ 12 was designed for use in the community and this may be one of the problems when using it in this study, whereas the HAD was designed for use in an hospital setting.

3.12. Feasibility of the Study and Sample Size

Prior to the commencement of the study, related literature on previous studies undertaken using massage and aromatherapy were examined to gain an indication of the number of patients needed to demonstrate any relationship between the variables. The previous years ICU patient admissions and discharge records were examined to determine the possible numbers of appropriate patients that could be recruited to the study, and the advice of a statistician was sought. The sample size was dependant on one researcher collecting data from one intensive care unit. The pilot study helped to verify the numbers of patients eligible for recruitment. A power calculation (see below) was undertaken which illustrated that 150 patients were required to demonstrate any effects. Patients were recruited at the rate of approximately six patients every month. Data was collected over three years due to maternity leave and the problems with patient recruitment previously mentioned.

3.12.1. Power Calculation

In order to determine the sample size required for the study, a power calculation was undertaken (Kirkwood 1992: 196-199), using The Hospital Anxiety and Depression

Scale (Zigmond and Snaith 1983), in order to demonstrate the desired significant effect of the study. Statistical advice was sought.

The calculation sought to determine the probability (power) of achieving a significance level at 5%. The HAD (Zigmond and Snaith 1993) was used as a basis for the power calculations. It was determined that a minimum of 120 patients were required to achieve an 80% probability at 5% significance, resulting in 40 patients in the control group, 40 patients in experimental group1 and 40 patients in experimental group 2 with an effect size of 0.7. It was acknowledged that there would be some loss of the sample during the study and therefore the sample size was increased to allow for possible non-response, loss to follow-up and death of patients during the study. A 10% drop out rate was incorporated into the calculation. A sample size of 150 was found to be adequate, resulting in;

Control	50 patients
Experimental 1	50 patients
Experimental 2	50 patients

3.13. Ethical Considerations

The ethical considerations raised by the study relate to the principle of respect for human dignity of the patients taking part in the research (Polit and Hungler 1993). The research was carried out in accordance with recognised standards of good clinical research practice, particularly 'The World Medical Association Declaration of Helsinki (1989)' regarding the use of biomedical research involving human subjects, and this was adhered to. The UKCC's Guidelines for Professional Practice (1996: 34-35), the UKCC's Professional Code of Conduct (1992), and the Scope of

Professional Practice (1992) were referred to and adhered to during this study. The ethical guidelines produced by the Royal College of Physicians (1996) were also adhered to.

3.13.1. Ethical Approval

Ethical approval was sought during March 1993, from the chairman of the ethics committee at the teaching hospital where the study took place, and was gained in June 1993 (appendix 8) following an amendment to the patient and relative information sheet.

Ethical issues were raised with regards to undertaking research in intensive care, the primary one being that patients are too ill to consent to be in a study and therefore relatives need to consent on their behalf.

3.13.2. Informed Consent

Informed consent is difficult to obtain from patients in intensive care as they usually present to intensive care with no prior knowledge of their admission, and their illness is usually so severe that they are sedated and ventilated and therefore are not in a position to give consent of any nature. In these cases the next of kin is asked to consent on behalf of the patient and this can increase the stress of relatives who are already feeling vulnerable. The patient if able, and/or the next of kin received an explanation about the study together with an information sheet (appendix 1), which included contact names and numbers of the researcher and the complementary nurse specialist within the hospital. Patients and/or their relatives were given time to consider participation in the study so that they were able to make an informed decision.

Consideration was given to the problem of gaining consent from the severely ill or unconscious patient (Royal College of Physicians 1990 pgs 23-26) who recognised this as another ethical problem. A recommendation by this report was utilised within the study, whereby patients who were unable consent to take part in the study were informed of the study as soon as they were conscious and asked if they would like to continue to participate.

3.13.3. Anonymity and Confidentiality

Anonymity was not possible for this study, as the researcher and the ICU staff were aware that each patient was involved in the study in order that data could be collected. To maintain confidentiality only patient initials were used and each patient was assigned a code for use in the study. This code was used throughout the study so that questionnaires would match patient data. An undertaking that findings would be written up so that no other person could be identified was assured. The purpose of the study was explained to all potential participants, and the need to complete two questionnaires at different time points was outlined by the researcher. The underlying principle of this was to give potential participants sufficient information to enable them to make an informed choice before committing themselves to involvement in the study. Patients or their next of kin were asked to sign a consent form to take part in the study (appendix 2) and were told that any information collected would be confidential. All completed data schedules and completed questionnaires were kept away from the research site, where only the researcher had access. Data entered for analysis did not permit the identification of any individual subject and was stored on a computer system away from the research site, and only the researcher had access to this information. The Data Protection Act (1984) was strictly adhered to.

3.16.4. The Right to Refuse and Withdraw from Participation

The Royal College of Physicians (1990 pgs 15-19) make explicit referral to the concept of patients being volunteers when involved in research, and refer to the Nuremberg code (1949) as being a useful statement of the conditions necessary for consent in the majority of patients. These codes were adhered to at all times.

Patients and their next of kin were given the right to refuse to take part in the research, and advised that participation was entirely voluntary. They were also informed of their choice to withdraw from the study at any time. Assurances were given that patients were free to decline to participate without giving a reason and that the decision would not affect patient care.

3.13.5. Protection from Harm

It was envisaged that there would be no adverse effects from using massage and/or bergamot oil 2.5%. Precautions were taken prior to the commencement of the study – skin patch test, stability of patient prior to massage. The bergamot oil used in this study was not thought to cause problems with photosensitivity when exposed to sunlight (Watts 1992). Also, patients within the intensive care are not exposed to sunlight.

No adverse effects were noted in the pilot study. A record was made of any adverse problems related to this study, and all recorded problems associated with using bergamot oil were taken into account i.e. the effects of photosensitivity when exposed to sunlight of some types of bergamot oil. A skin patch test was performed on each patient entering experimental group 2, to assess for sensitivity to bergamot oil 2.5%.

3.14. Data Management and Analysis

All data collected were coded and transferred onto a PC computer. SPSS PC for Windows (version 7.1) was used to analyse the data. Dependent measures of systolic blood pressure, diastolic blood pressure, mean blood pressure, heart rate, respiratory rate, quantity of analgesic drugs, quantity of anaesthetic drugs, anxiety, depression and quality of life variables were measured against the independent variable: group, to determine any differences. The effects of massage and aromatherapy massage were all measured against the dependent and independent variables.

Arithmetic means with standard deviations and ranges were calculated where appropriate. Simple relationships within the data have been examined using cross tabulations with significance assessed using Chi-squared statistics. A comparison was made between patients in the control group, experimental group 1 and experimental group 2 in relation to their demographic information, age, gender, diagnosis on admission and whether they had undergone surgery prior to ICU admission or not. ANOVA was used for continuous variables.

Differences between groups over time were identified using repeated measures multivariate analysis of variance (MANOVA). Analysis of variance (ANOVA) was used to identify differences between groups. The usual use of t-tests to compare means was not employed as the main statistical methodology within this thesis due to these tests only comparing two means and do not comprehensively acknowledge the intricacies of analysing three groups by comparing means in a comprehensive manner. Chi-square and logistical regression were used to measure the difference between groups in the use of analgesic drugs and anaesthetic drugs. For all the analyses, the statistical significance was set at the conventional 5% level. Missing data have been excluded for the totals reported within the results tables.

4 RESULTS

4.1 Introduction

The data were analysed and the results presented in two parts for clarity. The following pages describe the format of the chapter and explain how the data sets used in the analysis were compiled.

PART ONE

Part one is presented in two sections.

i. survival analysis

ii. descriptive and demographic data

PART TWO

Part two is presented in four sections.

i. the effects of massage only and aromatherapy massage on physiological variables of heart rate, blood pressure and respiratory rate

ii. the effects of massage only and aromatherapy massage on the quantity of analgesic drugs utilised and the levels of patients' pain

iii. the effects of massage only and aromatherapy massage on the quantity of anaesthetic drugs utilised and the levels of patients' consciousness

iv the effects of massage only and aromatherapy massage on psychological variables of depression, anxiety and quality of life after discharge from ICU.

PART ONE

Section One: Survival Analysis

A survival analysis was undertaken to determine which data would be most appropriate to analyse. This was undertaken by examining the patient loss from the whole data set over the time of the study and determining adequate sample sizes for analysis. This resulted in three data sets; whole data set, data set A and data set B.

Section Two: Demographic and descriptive data.

The demographic and descriptive data have been presented as an analysis of the whole data set, data set A and data set B. Firstly a descriptive analysis of the independent variables was presented and secondly the relationships between the dependent variables and the independent variables were investigated and presented.

PART TWO

Sections One - Four

Sections one to four have been presented as an analysis of each hypothesis using data set A and data set B. For each of these sections the following analysis was applied. First, a descriptive analysis of the dependent variable and then each of the independent variables was presented and secondly, the relationships between the dependent variable and independent variables were investigated.

When investigating hypotheses one to three, data sets A and B were used, however when investigating hypothesis four the whole data set was utilised. This was because patients in data set A and data set B only received one or two massages and these criteria could not be applied to hypothesis four because by the time patients were discharged from ICU they may have received more than one massage in a random order (ie not restricted to the first or second massage).

The following hypotheses were examined in each of the sections below. A tabular presentation was adopted for clarity. Table 4.1.

Table 4.1 Data analysed in parts one and two

Part	Section	Objective of data analysis	Data analysed
ONE	One	To undertake survival analysis	whole data set
	Two	To analyse the demographic and descriptive data	whole data set data set 1 data set 2
TWO	One	To address hypothesis one; Patients in intensive care receiving massage or aromatherapy massage will demonstrate a reduction in blood pressure, heart rate and respiratory rate than those patients in the control group	data set 1 data set 2
	Two	To address hypothesis two; Patients in intensive care receiving massage or aromatherapy massage will require less analgesic drugs than those in the control group	data set 1 data set 2
	Three	To address hypothesis three; Patients in intensive care receiving massage or aromatherapy massage will require less anaesthetic drugs than those in the control group.	data set 1 data set 2
	Four	To address hypothesis four; Patients in intensive care receiving massage or aromatherapy massage will have reduced anxiety and depression scores, and will demonstrate an improved quality of life on discharge and at one month discharge from intensive care than those in the control group.	whole data set

4.1.1 Selection of data sets

One method of determining the effect of massage only and aromatherapy massage on patients who are critically ill was to examine the group of patients who had received consecutive massages following admission to ICU. Patients in the experimental groups who were unable to receive consecutive massages or aromatherapy massages due to the exclusion criteria applied at the assigned time of massage were excluded from the data analysis. This enabled the groups utilised in the analysis to be comparable (ie they all received the same number of massages at the same time points).

A survival analysis was undertaken which determined the attrition rates from the control and experimental groups. As time progressed the loss to each of the groups declined steeply. The sample population which fulfilled the criteria of having consecutive massage only or aromatherapy massage and contained adequate sample sizes to analyse, emerged as the group of patients who received the intervention on day two and day five of their stay in ICU. This resulted in three data sets to be analysed.

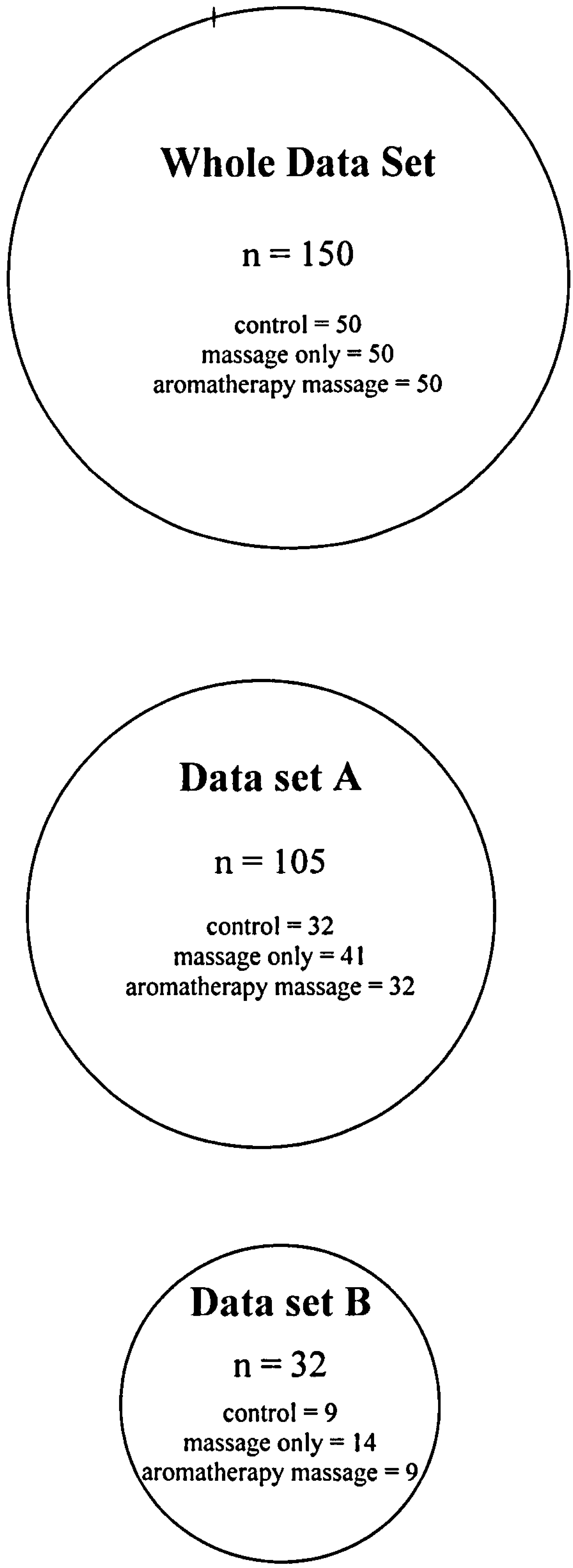
Whole Data set (all patients recruited to the study)

Data set A (the group of patients who received the first intervention)

Data set B (the group of patients who received the first and second intervention)

The two subgroups, data set A and data set B were selected to analyse and this enabled comparisons of similar groups of patients to be made. Three intervention episodes could not be analysed, as a substantial loss in patients would make statistical analysis untenable. This was confirmed following statistical advice. Figure 4.1.

Figure 4.1 Data sets used in analysis



4.1.2 Definitions

Whole Data set: the whole data set consisted of all data for patients that were admitted to the study during the study period and who were randomly allocated to one of three study groups; control, massage only or aromatherapy massage.

Data set A (one intervention): the whole data set was filtered to produce data set A which consisted of those patients who received the first intervention on day two of their stay in ICU.

Data set B (two interventions): the whole data set was filtered to produce data set B which included those patients who received the first and second consecutive intervention on day two and day five of their stay in ICU.

Intervention

The intervention consisted of either massage only or aromatherapy massage dependent on which group the patients had been randomly allocated to. In the case of the control group there was no intervention but the patients were subjected to all other experimental conditions. The patient received the intervention every third day of their stay in ICU commencing on day two. The interventions for each group were as follows;

control group: no intervention

experimental 1 group: massage only

experimental 2 group: aromatherapy massage

Intervention Exclusion Criteria

Two nurses independently reassessed all patients recruited to the study prior to receiving the intervention. This was to ensure that the patient had not deteriorated following admission to ICU and remained in a condition suitable to receive the intervention. Therefore a set of exclusion criteria was used immediately prior to the intervention to ensure patients were suitable. The exclusion criteria were;

- too unstable or poorly as assessed by the nurse at the bedside, such that their condition would deteriorate or was life threatening
- too busy ie the patient was receiving many interventions
- pyrexial, the patients temperature was above 38^0c
- presence or suspicion of emboli
- patient refused
- patient was receiving another intervention eg line insertion, tracheostomy
- patient was in theatre undergoing a surgical procedure

Patients who fulfilled the exclusion criteria at the time of the intervention were excluded for that time point.

Note: the control group was subjected to the same exclusion criteria as the massage only and aromatherapy massage groups at the time of the intervention to ensure that the same experimental conditions existed between the three groups.

Diagnosis

Patients' primary diagnoses on admission to the ICU were classified using the International Classification of Diseases (1960). Nine potential primary diagnoses were identified, cardiovascular, gastro-intestinal, neurological, respiratory, renal, haematological, metabolic and burns. Patients admitted to the study were all classified within four of the categories; cardiovascular, respiratory, respiratory and renal.

Drugs

i. Anaesthesia.

Anaesthesia is a loss of feeling or sensation in a part or in the whole of the body usually induced by drugs. It is commonplace to administer several drugs with different actions to produce a state of surgical anaesthesia with minimal risk of toxic effects

Propofol (diprivan) is manufactured by AstraZeneca. Propofol was manufactured for induction and maintenance of general anaesthesia. In intensive care propofol is used to maintain patients in a steady state of sleep to minimise complications and is therefore administered as a continuous infusion until the patient is well enough to commence to be woken up.

Midazolam (hypnovel) is manufactured by Roche. Midazolam is a water soluble benzodiazepine and causes sedation with amnesia. Midazolam is often used in combination with propofol.

ii.Analgesia

Analgesia is an insensibility to pain which can be induced by analgesic drugs which are remedies that relieve pain.

Morphine sulphate is an opioid analgesic used to relieve moderate to severe pain. It is administered to patients who have undergone a surgical procedure and patients who are in pain for a variety of reasons. In intensive care morphine sulphate is used regularly to relieve pain. It is administered in a continuous infusion and the rate of infusion is controlled by the medical and nursing team.

Alfentanil (rapifen) is an opiod anaesthetic manufactured by Janssen. It is also used to enhance anaesthesia. In intensive care its primary use is for analgesia and suppression of respiratory activity for patients who are ventilated. It is administered intravenously by continuous infusion.

Bupivacaine hydrochloride (marcain) is manufactured by AstraZeneca. Bupivacaine hydrochloride is used as a continuous epidural infusion and has a duration of action of between two and three hours. In intensive care it is administered as a continuous infusion, the rate of which is mainly controlled by the patient.

4.2 Part One

4.2.1 Section One: Survival Analysis

4.2.1.1 Attrition of patients from experimental and control groups

A survival analysis was undertaken to determine the attrition of patients from the study. Patients were lost from the study due to an inability to receive the intervention on the given day because strict exclusion criteria were imposed prior to every massage (because patients condition can change rapidly), death in ICU and discharge from ICU.

The survival analysis focused on the occurrence of the intervention and the time until that event for each case recruited to the study. The term 'survival time' in the analysis referred to 'time to the event of interest' (Kirkwood 1992) and in this study that equated with 'time to the next intervention'.

A life table (table 4.2) was constructed to determine the rate of loss from the three groups of patients (control, massage only and aromatherapy massage) following recruitment to the study.

Table 4.2 Life table of patients recruited to study

	Control	Massage only	Aromatherapy massage	Total
Recruitment	**n = 50**	**n = 50**	**n = 50**	**n = 150**
loss to intervention (day 2) due to;				
discharge	0	0	0	0
death	0	0	0	0
exclusion criteria	18	9	18	45
total interval loss	18	9	18	45
First Intervention Data set A	**32**	**41**	**32**	**105**
loss to intervention (day 5) due to;				
discharge	16	12	11	39
death	3	1	3	7
exclusion criteria	4	14	9	27
total interval loss	23	27	23	73
First and Second Intervention Data set B	**9**	**14**	**9**	**32**

Bold - remaining sample
Not bold - loss from sample

The life table demonstrated that the main loss of patients from the study was due to the exclusion criteria imposed at the time of the intervention. At the time of the first intervention this accounted for 18 (36%) patients in the control group, nine (18%) patients in the massage only group and 18 (36%) patients in the aromatherapy massage group and accounted for a further four (13%) patients in the control group, 14 (34%) in the massage only group and nine (28%) patients in the aromatherapy massage group at the time of the second intervention.

Between the first intervention and the second intervention there was a substantial loss from data set A as a result of discharges from the ICU, n=39 (37%) patients. Sixteen (50%) patients from the control group, 12 (29%) patients from the massage only group and 11 (34%) patients from the aromatherapy massage group were discharged from the ICU. There was a minimal loss at this time point due to death (n=7, 1%). Three (1%) patients in the control group and three (1%) patients in the aromatherapy massage groups died, whilst one (1%) patient died from the massage only group. In total, between recruitment and the second intervention a total of 118 (79%) patients were lost from the study; 41 (82%) from the control group, 36 (72%) from the massage only group and 41 (82%) from the aromatherapy massage group. Table 4.2.

A more complex life table (table 4.3) which details the whole sample from recruitment to the study to the end of the study showed the reduction in patient numbers over the first two interventions and demonstrated that few patients continued in the study until day 57 when the final patient exited the ICU.

Kaplan-Meier curves demonstrated the survival of each group in the study. Survival in this instance means time to death or discharge from ICU. The massage only group spent the least time on the ICU with a mean of 10 days (SD = 10.16, range 2 to 50 days), the control group survived a mean time of 12 days (SD = 12.03, range 2 to 56 days) on the ICU and the aromatherapy massage group survived a mean of 11 days (SD = 10.01, range 2 to 40 days).

Table 4.3 Life table showing the survival pattern of 150 patients (whole sample) recruited to the study

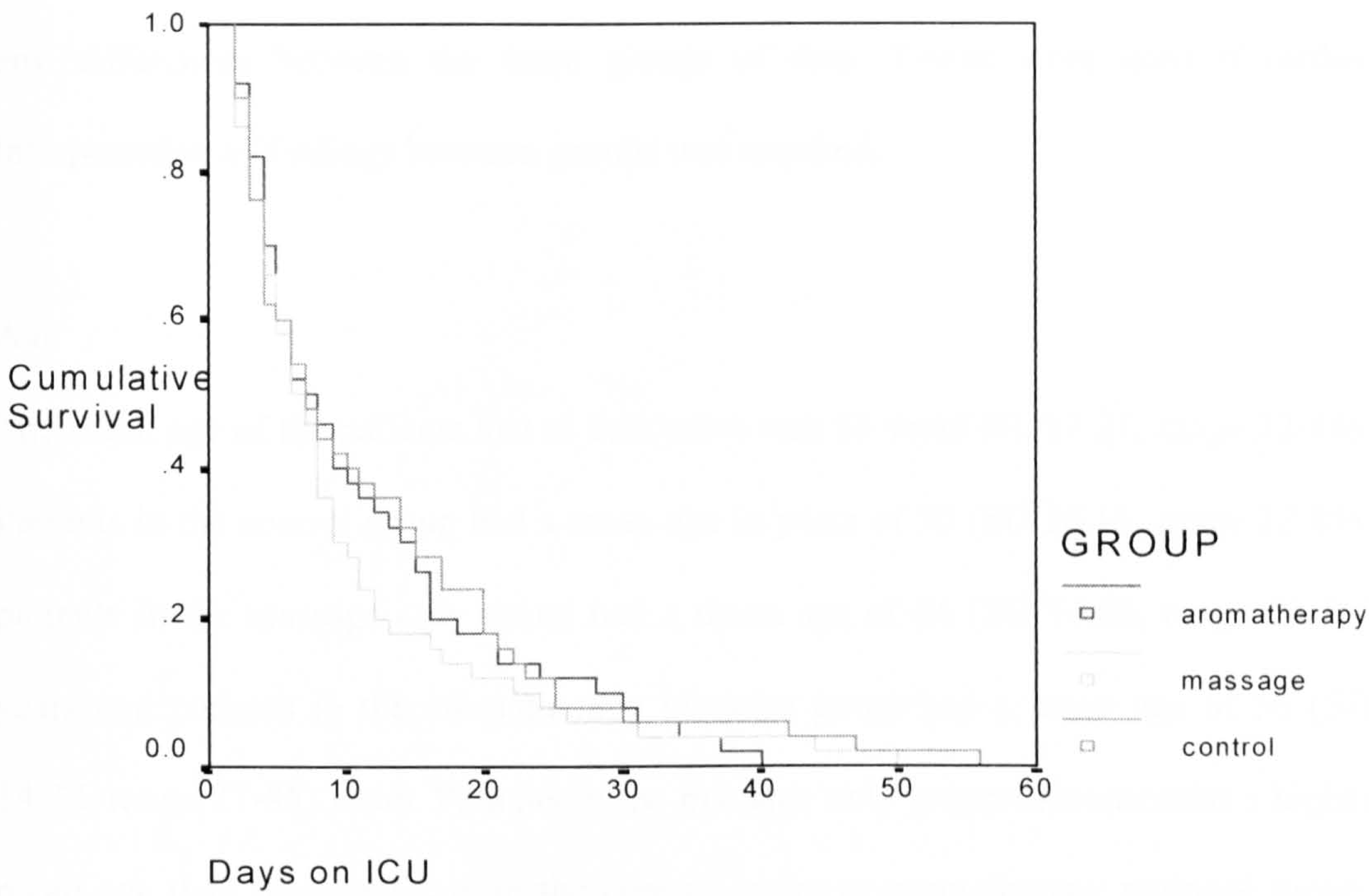
Interval since start of study (days)	Number in ICU at beginning of interval			Discharges during interval			Deaths during interval			Number lost to follow-up during interval		
	C	M	A	C	M	A	C	M	A	C	M	A
2	50	50	50	0	0	0	0	0	0	0	0	0
5	31	33	35	15	13	11	3	3	5	18	16	16
8	24	23	25	2	6	5	5	6	1	7	12	6
11	20	14	19	2	2	2	0	4	1	2	6	3
14	18	9	16	1	3	2	3	1	2	4	4	4
17	14	8	10	2	0	4	2	2	1	4	2	5
20	12	6	9	2	1	1	0	0	0	2	1	1
23	10	5	8	1	0	2	2	1	0	3	1	2
26	7	4	6	2	1	0	0	1	1	2	2	1
29	5	2	5	0	0	1	0	0	0	0	0	1
32	5	2	4	1	1	1	0	0	1	1	1	2
35	4	1	2	0	0	1	0	0	0	0	0	1
38	4	1	1	0	0	0	0	0	1	0	0	1
41	4	1	0	1	0	0	0	0	0	1	0	0
44	3	1	0	0	0	0	1	0	0	1	0	0
47	2	1	0	0	0	0	0	0	0	0	0	0
50	2	1	0	0	0	0	1	0	0	0	1	0
53	2	0	0	0	0	0	1	0	0	1	0	0
56	1	0	0	1	0	0	0	0	0	1	0	0
59	0	0	0	0	0	0	0	0	0	0	0	0

C = control M = massage A = aromatherapy massage

The maximum range and the Kaplan-Meier curves demonstrated that the aromatherapy massage group were all discharged or had died by 40 days whilst one patient from the control group still remained on ICU until 57 days. This was the longest time a patient in the study spent on the ICU. The longest time a patient from the massage only group remained on the ICU was 50 days. Graph 4.1.

The use of analysis of variance demonstrated no significant differences between the three experimental groups of patients regarding the mean survival time in ICU.

Graph 4.1 Kaplan-Meier survival curve for patients whilst on ICU.



4.2.1.2 Comparison of loss from whole data set to data set A

The loss of patients from the whole data set (n=150) to data set A (n=105) consisted of 45 (30%) patients. All patients lost from the analysis at this time point were due to the massage exclusion criteria being imposed at the time of the intervention. There was a loss of 18 (12%) patients from the control group, 9 (6%) patients from the massage only group and 18 (12%) patients from the aromatherapy massage group. Table 4.4.

Table 4.4 Loss of patients from whole data set to data set A by group

	Control	Massage only	Aromatherapy Massage	Total
Whole data set	50 (33%)	50 (33%)	50 (33%)	150 (100%)
Data set A	32 (21%)	41 (28%)	32 (21%)	105 (70%)
Loss	18 (12%)	9 (6%)	18 (12%)	45 (30%)

Univariate analysis of variance (ANOVA) and chi-squared was used to determine any differences between the three groups of data. T-tests were used if further interpretation of findings between groups was required.

Age

The mean age of the patients lost to data set A was 55 years (SD17.31, range 22-86). Patients in the control group had a mean age in years of 50 (SD 20.16, range 22-85), patients in the massage only group had a mean age of 64 (SD 14.66, range 36-76) years and patients in the aromatherapy massage group had a mean age of 56 (SD 14.32, range 27-86) years. Patients in the massage only group demonstrated a higher mean age than those patients in the control group or aromatherapy massage group. Table 4.4.1.

Table 4.4.1 Age of patients lost from whole data set to data set A by group: values are expressed as Mean (SD)

	Control (n=18)	Massage only (n=9)	Aromatherapy Massage (n=18)	Total (n=45)
Mean age in years (SD)	50 (20.16)	64 (14.66)	56 (14.32)	55 (17.31)
Range	22 - 85	36 - 76	27 - 86	22 - 86

The use of ANOVA demonstrated no significant differences between the three groups of patients lost to data set A in terms of their mean age in years. There was no significant difference between patients lost to data set A compared to patients in the whole data set in terms of their mean age in years.

APACHE 11 score

The mean APACHE 11 score of patients lost to data set A was 21 (SD 7.13, range 7 to 40). Patients in the control group had a mean APACHE 11 score of 20 (SD 6.9, range 7-34), patients in the massage only group had the highest mean APACHE 11 score of 23 (SD 9.73, range 13-40) and patients in the aromatherapy massage group had a mean APACHE 11 score of 21 (SD 5.92, range 12-35). Table 4.4.2.

Table 4.4.2 APACHE 11 of patients lost from whole data set to data set A by group: values are expressed as Mean (SD)

	Control (n=18)	Massage (n=9)	Aromatherapy Massage (n=18)	Total (n=45)
Mean APACHE 11 scores (SD)	20 (6.9)	23 (9.73)	21 (5.92)	21 (7.13)
Range	7 - 34	13 - 40	12 - 35	7 - 40

The use of ANOVA demonstrated there were no significant differences between the three groups of patients lost to the analysis in terms of their mean APACHE 11 scores. There was no significant difference between the groups of patients lost to data set A and patients in the whole data set in terms of their mean APACHE 11 scores.

Gender

There were 28 (62%) males and 17 (38%) females lost to data set A. There was more than double the number of male patients (n=13, 72%) lost in the control group compared to female patients (n=5, 18%). Almost equal numbers of male and female patients were lost to data set A in the massage only group (male; n=5, 55%, female; n=4, 45%) and the aromatherapy massage group (male; n=10, 56%, female n=8, 44%). Table 4.4.3.

Table 4.4.3 Gender of patients lost to from whole data set to data set A by group

	Gender		Total
	Male	Female	
Control	13 (72%)	5 (18%)	18 (40%)
Massage only	5 (55%)	4 (45%)	9 (20%)
Aromatherapy massage	10 (56%)	8 (44%)	18 (40%)
Total	28 (62%)	17 (38%)	45 (100%)

The use of chi-squared showed there were no significant differences between the three groups of patients lost from the analysis in terms of their gender. There were no significant differences between the patients lost to data set A and the patients in the whole data set in terms of their gender.

Diagnoses

Respiratory illnesses represented the largest group of patients (18; 40%), which were lost to data set A. The remaining loss of patients to the other diagnostic groups comprised of those with cardiovascular n=15 (33%), gastrointestinal n=10 (22%) and renal n=2 (5%) diseases. Table 4.4.4.

The use of chi-squared demonstrated that there were no significant differences between the three groups of patients, which were lost to data set A in terms of their diagnosis on admission to ICU. There were no significant differences between the patients lost to data set A and the patients in the whole data set in terms of their diagnosis.

Table 4.4.4 Diagnoses of patients lost from whole data set to data set A by group

	DIAGNOSES				
	Cardio-vascular	Gastro-intestinal	Respiratory	Renal	Total
Control	6 (40%)	3 (30%)	8 (44%)	1 (50%)	18 (40%)
Massage only	3 (20%)	1 (10%)	4 (22%)	1 (50%)	9 (20%)
Aromatherapy massage	6 (40%)	6 (60%)	6 (33%)	0	18 (40%)
Total	15 (33%)	10 (22%)	18 (40%)	2 (5%)	45 (100%)

Surgical status

Of the 45 (30%) patients lost from the whole data set to data set A, 21 (47%) of these patients were admitted to ICU from theatre and 24 (53%) patients were admitted from A&E or from a ward. In each of the three experimental groups almost equal numbers were lost from those who had undergone a surgical procedure immediately prior to admission and those who had not. Ten (56%) patients from the control group had undergone a surgical procedure prior to admission to ICU and eight (44%) patients had been admitted from A&E or from the wards. Four patients (45%) from the massage only group were admitted from theatre and five (55%) patients from A&E or from the wards. Table 4.4.5.

Table 4.5.5 Surgical status of patients lost from whole data set to data set A by group

	Non surgical	Surgical	Total
Control	8 (44%)	10 (56%)	18 (40%)
Massage only	5 (55%)	4 (45%)	9 (20%)
Aromatherapy massage	11 (61%)	7 (39%)	18 (40%)
Total	24 (53%)	21 (47%)	45 (100%)

Finally in the aromatherapy massage group seven (39%) patients had undergone a surgical procedure prior to ICU admission and 11 (61%) patients were admitted from A&E or from the wards.

The use of chi-squared demonstrated there were no significant differences between the three groups of patients that were lost from the whole data set to data set A in terms of whether they had undergone a surgical procedure in theatre prior to ICU admission or not. There were no significant differences between the patients lost to data set A and the patients in the whole data set in terms of whether the patients had undergone a surgical procedure in theatre or not prior to admission.

Summary of loss to data set A

The sub-set of patients (n=45) who were lost from data set A showed no significant differences in any demographic characteristics compared to those patients recruited to the whole study (n=150) or to those patients recruited to data set A (n=105). The greatest loss of patients was from the control group (n=18) and the aromatherapy massage group (n=18). The least loss of patients was from the group who received massage only (n=9).

4.2.1.3 Comparison of loss from whole data set to data set B

The loss of patients from the whole data set (n=150) to data set B (n=32, 21%) was 118 (79%) patients. Those patients lost from the sample consisted of 41 (27%) patients from the control group, 36 (25%) patients from the massage only group and 41 (27%) patients from the aromatherapy massage group. The majority of patients lost from the analysis at this time point were due to the massage exclusion criteria being imposed at the time of the intervention (n=72, 61%). Twenty-two (54%) patients were lost from the control group, twenty-three (64%) patients were lost from the massage only group and twenty-seven (66%) patients were lost from the aromatherapy massage group. Patients were also lost from the whole data set, to data set B as a result of discharge (n=39, 33%) and death (n=7, 6%). Table 4.5.

Table 4.5 Loss of patients from whole data set to data set B by group

		Control	Massage only	Aromatherapy Massage	Total
Whole data set		**50 (33%)**	**50 (33%)**	**50 (33%)**	**150 (100%)**
Data set B		**9 (18%)**	**14 (28%)**	**9 (18%)**	**32 (21%)**
Loss due to	Discharge	16 (39%)	12 (33%)	11 (27%)	39 (33%)
	Death	3 (7%)	1 (3%)	3 (7%)	7 (6%)
	Exclusion criteria	22 (54%)	23 (64%)	27 (66%)	72 (61%)
Total Loss		**41 (82%)**	**36 (72%)**	**41 (82%)**	**118 (78%)**

Age

The mean age of the patients lost to data set B was 60 years (SD 15.87, range 21-87). Those patients lost from the control group had a mean age of 56 years (SD 27.91, range 21-85), patients from the massage only group had a mean age of 64 years (SD 13.27, range 31-87) years and patients from the aromatherapy massage group had a mean age of 59 years (SD 15.31, range 24-86).

Table 4.5.1 Age of patients lost from whole data set to data set B by group: values are expressed as Mean (SD)

	Control (n=41)	Massage only (n=36)	Aromatherapy Massage (n=41)	Total (118)
Mean age in years (SD)	56 (27.91)	64 (13.27)	59 (15.31)	60 (15.87)
Range	21 - 85	31 – 87	24 - 86	21 - 87

The use of ANOVA demonstrated no significant differences between the three groups of patients lost to data set B in terms of their age in years. There was no significant difference between the groups of patients lost to data set B and patients in the whole data set in terms of their mean age in years.

APACHE 11 score

The mean APACHE 11 score of patients lost to data set B was 20 (SD 5.97, range 7 to 40). Patients lost from the control group had a mean APACHE 11 score of 19 (SD 5.95, range 7-34), patients lost from the massage only group had the highest mean APACHE 11 score of 21 (SD 6.43, range 8-40) and patients lost from the aromatherapy massage group had a mean APACHE 11 score of 20 (SD 5.62, range 7-35). Table 4.5.2.

Table 4.5.2 APACHE 11 of patients lost from whole data set to data set B by group: values are expressed as Mean (SD)

	Control (n=41)	Massage (n=36)	Aromatherapy Massage (n=41)	Total (n=118)
Mean APACHE 11 scores (SD)	19 (5.95)	21 (6.43)	20 (5.62)	20 (5.97)
Range	7 - 34	8 - 40	7 - 35	7 - 40

The use of ANOVA demonstrated no significant differences between the three groups of patients lost to data set B in terms of their mean APACHE 11 scores. There was no significant difference between the groups of patients lost to data set B compared with patients in the whole data set in terms of their mean APACHE 11 score.

Gender

There were 62 (53%) males and 56 (47%) females lost from the whole data set to data set B. There was more than double the number of male patients (n=28, 68%) lost in the control group compared to female patients (n=13, 32%). Equal numbers of male and female patients were lost from data set B in the massage only group (male; n=18, 50%, female; n=18, 50%). However in the aromatherapy massage group there were more female patients (n=25, 61%) lost in data set B than male patients (male; n=16, 39%). The use of chi-squared demonstrated a significant difference between the three experimental groups of patients lost from data set B in terms of their gender. The proportion of females lost varied by group, $\chi^2 = 7.18$, df = 2, p = 0.03. Further analysis of this result using t-tests showed the difference was between patients in the control group and patients in the aromatherapy massage group (p = 0.01) demonstrating a significant difference in the number of male and female patients in each group. Table 4.5.3.

Table 4.5.3 Gender of patients lost from whole data set to data set B by group

	Gender		Total
Group	Male	Female	
Control	28 (45%)	13 (23%)	41 (35%)
Massage only	18 (30%)	18 (32%)	36 (30%)
Aromatherapy massage	16 (25%)	25 (45%)	41 (35%)
Total	62 (53%)	56 (47%)	118 (100%)

There were no significant differences between the patients lost to data set B and the patients in the whole data set in terms of their gender.

Diagnoses

Patients with respiratory illnesses represented the largest group (49; 42%) lost to data set B. The remaining loss of patients to the other diagnostic groups comprised of those with cardiovascular n=37 (31%), gastrointestinal n=28 (24%) and renal n=4 (3%) diseases. The use of chi-squared demonstrated no significant differences between the three groups of patients that were lost to data set B in terms of their diagnosis on admission to ICU. Table 4.5.4.

Table 4.5.4 Diagnoses of patients lost from whole data set to data set B by group

	DIAGNOSIS				
	Cardio-vascular	Gastro-intestinal	Respiratory	Renal	Total
Control	13 (31%)	12 (29%)	14 (34%)	2 (6%)	41 (35%)
Massage only	10 (28%)	6 (16%)	19 (53%)	1 (3%)	36 (30%)
Aromatherapy massage	14 (34%)	10 (24%)	16 (39%)	1 (3%)	41 (35%)
Total	37 (31%)	28 (24%)	49 (42%)	4 (3%)	118 (100%)

There were no significant differences between the patients lost to data set B and the patients in the whole data set in terms of their diagnosis.

Surgical status

Of the 118 (79%) patients lost from the whole data set to data set B, 62 (53%) of these patients were admitted to ICU from theatre and 56 (47%) patients were admitted from A&E or from a ward. In the massage only and the aromatherapy massage groups almost equal numbers were lost from those groups of patients who had undergone a surgical procedure immediately prior to admission and those who had not. Seventeen (47%) patients from the massage only group were admitted from theatre and nineteen (53%) patients from A&E or from the wards. Twenty one (51%) patients in the aromatherapy massage group had undergone a surgical procedure prior to ICU admission and twenty (49%) patients were admitted from A&E or from the wards. More patients (n=24, 59%) from the control group had undergone a surgical procedure prior to admission to ICU than those patients who had been admitted from A&E or from the wards (n=17, 41%). Table 4.5.5.

Table 4.5.5 Surgical status of patients lost from whole data set to data set B by group

Group	Non surgical	Surgical	Total
Control	17 (41%)	24 (59%)	41 (35%)
Massage only	19 (53%)	17 (47%)	36 (30%)
Aromatherapy massage	20 (49%)	21 (51%)	41 (35%)
Total	56 (47%)	62 (53%)	118 (100%)

The use of chi-squared demonstrated no significant differences between the three groups of patients that were lost from the whole data set to data set B in terms of whether they had undergone surgery prior to ICU admission or not. There were no significant differences between the patients lost to data set B and the patients in the whole data set in terms of whether the patients had undergone surgery or not prior to admission.

Summary of loss to data set B

The sub-set of patients (n=118) who were lost from data set B showed no significant differences in any demographic characteristics compared to those patients recruited to the whole study (n=150). One significant difference between the three groups of patients in data set B was found in relation to gender. This difference was significant between patients lost from the control group and patients lost from the aromatherapy massage group at the 1% level ($p<0.01$).

4.2.1.4 Patients admitted to ICU and not recruited to the study

Information was collected regarding the patient group who were not recruited to the study. Patients were not recruited to the study for the following reasons, inability to obtain consent from either the patient or relative, patients or relative refusal to be part of the study and it was deemed probable by both medical and nursing staff that the patient was unlikely to survive their stay in ICU due to the seriousness of the patients illness. Table 4.6.

Table 4.6 Patients admitted to ITU and not recruited to study

Reason for not recruiting patient into study	Number of Patients				
	1994	1995	1996	1997	Total
Patient likely to be discharged within 2 days of admission	304	330	255	463	1352
Legs inaccessible	15	26	22	18	81
Unable to obtain consent	5	5	6	3	19
Patient unlikely to survive	81	98	95	110	384
Total not recruited by year	405	459	378	594	1836

4.2.1.5 Summary of section one

A proportion of patients were lost from the analysis due to, exclusion criteria applied at time of massage, discharge from ICU and death. This group of patients consisted of 45 (30%) patients lost from the whole data set to data set A, and 118 (79%) patients lost from the whole data set to data set B. There were no significant differences between those patients lost from both data set A and data set B, and the whole data set. There were also no significant differences between the three groups of patients lost to data set A. However there was one significant difference between the three groups of patients lost to data set B in terms of their gender. Patients in the control group and patients in the aromatherapy massage group demonstrated a significant difference between the numbers of patients in each group in terms of their gender at the 1% level (p>0.01).

The survival analysis enabled the data sets to be developed for analysis and demonstrated that the intervention did not influence the death rate or length of stay of patients in ICU who were recruited into the study.

4.2.2 Section Two: Demographic and Descriptive Data

The demographic and descriptive data have been presented in the following parts; whole data set, data set A and data set B.

4.2.2.1 Whole Data Set

A total of 150 patients admitted to ICU during the study period were recruited and randomly allocated to one of three study groups. Table 4.7.

Table 4.7. Allocation of patients to study groups

Control	Massage only	Aromatherapy Massage	Total
n = 50 (33%)	n = 50 (33%)	n = 50 (33%)	n = 150 (100%)

Demographic and descriptive data from the three groups of patients were analysed to determine if there were any similarities and differences between them. Data are presented for age, social class, life events, APACHE 11 score, gender, diagnosis and surgical status. Data relating to age, social class, life events and APACHE 11 were analysed using ANOVA. Nominal data relating to gender, diagnosis and surgical status were analysed using chi-squared. Any differences were further examined using t-tests.

Age

The mean age of patients recruited to the study was 60 years (SD 15) with a range of 66 (21-87). The mean age, standard deviations and ranges of the mean age of patients in each group are shown below in table 4.7.1. There were no statistically significant differences between the three groups in terms of their age.

Table 4.7.1 Ages of patients in whole data set by group: values are expressed as Mean (SD)

	Control (n=50)	Massage only (n=50)	Aromatherapy Massage (n=50)	Total (n=150)
Mean age in years (SD)	57 (17.33)	64 (13.78)	60 (15.43)	60 (15)
Range	21 - 85	31 - 87	24 - 86	21 - 87

Social Class

The information obtained regarding the current employment of patients (OPCS 1995) related to 110 (73%) patients. There were 40 (27%) missing cases. The majority of patients (n=53, 48%) belonged to social class IV, whilst the fewest number of patients were in social class III (n=10, 9%). Patients were evenly distributed throughout the remaining categories. Table 4.7.2. There were no significant differences between the three subgroups with regards to social class.

Table 4.7.2 Social class status (OPCS 1995) of patients in whole data set by group

Social Class	Control	Massage only	Aromatherapy massage	Total
I	7 (59%)	2 (16%)	3 (25%)	12 (10%)
II	3 (16%)	8 (45%)	7 (39%)	18 (17%)
III	4 (40%)	0	6 (60%)	10 (9%)
IV	18 (33%)	21 (40%)	14 (27%)	53 (49%)
V	6 (35%)	6 (35%)	5 (30%)	17 (15%)
Total	38 (35%)	37 (34%)	35 (31%)	110 (100%)

Life Events

Ninety (60%) patients or their next of kin completed the social readjustment rating scale indicating the level of stress in their lives over the previous year. The mean life events score of patients recruited to the study was 157 (SD 98) with a range of 573 (12-585). Patients in the control group demonstrated the highest mean score of 192 (SD 129). These patients also had the largest range of scores; 560 (25-585) suggesting that this group of patients may have been exposed to a greater number or more severe stressful life events in the year prior to admission. Patients in the massage only group demonstrated the lowest mean score of 127 (SD 75) and the lowest range of 337 (12-349). Patients in the aromatherapy massage group had a mean score of 157 (SD 79) with a range of 305 (40-345). Table 4.7.3. The non-parametric test, Kruskal Wallis was used to determine any differences between the three groups in terms of the life events score due to the outlier in the control group indicated by the large standard deviation compared to the mean. There were no significant differences between the three groups, X^2=5.19, df2, p=0.075.

Table 4.7.3 Life Events scores of patients in whole data set by group: values are expressed as Mean (SD)

	Control (n=27)	Massage only (n=30)	Aromatherapy Massage (n=33)	Total (n=90)
Mean life events score (SD)	192 (129)	127 (75)	157 (79)	157 (98)
Range	25 - 585	12 - 349	40 - 345	12 - 585

APACHE 11

The mean APACHE 11 score of patients recruited to the study was 19 (SD 6) with a range of 33 (7-40). The mean APACHE 11 score, standard deviations and ranges of the mean APACHE 11 score for each subgroup are shown below in table 4.7.4. There were no statistically significant differences between the three subgroups in terms of APACHE 11 score, demonstrating that all the groups were of a similar severity of illness on admission to ICU.

Table 4.7.4 APACHE 11 scores of patients in whole data set by group: values are expressed as Mean (SD)

	Control (n=50)	Massage only (n=50)	Aromatherapy Massage (n=50)	Total (n=150)
Mean APACHE 11 scores (SD)	20 (6.4)	20 (6.1)	19 (5.5)	20 (6)
Range	7 - 34	8 - 40	7 - 35	7 - 40

Gender

Seventy six (51%) patients recruited to the study were male and 74 (49%) were female. The control group had 31 (62%) male patients and 19 (38%) female patients. The massage only group had equal numbers of male and female patients (n=25, 50%) and the aromatherapy massage group had more female patients (n=30, 60%) than male patients (n=20, 40%). Table 4.7.5. There were no significant differences between the three groups in terms of gender.

Table 4.7.5 Gender of patients in whole data set by group

	Gender		Total
Group	Male	Female	
Control	31 (62%)	19 (38%)	50 (33%)
Massage only	25 (50%)	25 (50%)	50 (33%)
Aromatherapy massage	20 (40%)	30 (60%)	50 (33%)
Total	76 (51%)	74 (49%)	150 (100%)

Diagnoses

Patients with respiratory illnesses represented the largest group (n=65 43%). Patients with cardiovascular illnesses (n=43 29%) and gastrointestinal illnesses (n=38 25%) also represented a large proportion of patients. Patients with renal diseases accounted for only four patients (3%). The numbers and percentages of patients represented in each of the subgroups are shown in table 4.7.6. There were no significant differences between the three groups in terms of their diagnosis on admission to ICU.

Table 4.7.6 Diagnoses of patients in whole data set by group

	DIAGNOSIS				
Group	Cardio-vascular	Gastro-intestinal	Respiratory	Renal	Total
Control	15 (30%)	17 (34%)	16 (32%)	2 (4%)	50 (33%)
Massage only	12 (24%)	10 (20%)	27 (54%)	1 (2%)	50 (33%)
Aromatherapy massage	16 (32%)	11 (22%)	22 (44%)	1 (2%)	50 (33%)
Total	43 (29%)	38 (25%)	65 (43%)	4 (3%)	150 (100%)

Surgical Status

Eighty (53%) patients recruited to the study were admitted from theatre following a surgical procedure and 70 (47%) were admitted directly from the accident and emergency department or from a ward within the hospital. Similar numbers of patients were recruited from both a surgical and non surgical background to the three groups. The control group had more patients with a surgical background (n=31; 62%) than with a non surgical background (n=19; 38%), whilst the massage group had more non surgical patients (n=27; 54%) than surgical patients (n=23; 46%). The aromatherapy group had almost equal numbers of surgical (n=26; 52%) and non surgical patients (n=24; 48%). Table 4.7.7.

Table 4.7.7 Surgical status of patients in whole data set by group.

Group	Non surgical	Surgical	Total
Control	19 (38%)	31 (62%)	50 (33%)
Massage only	27 (54%)	23 (46%)	50 (33%)
Aromatherapy massage	24 (48%)	26 (52%)	50 (33%)
Total	70 (47%)	80 (53%)	150 (100%)

There were no significant differences between the three groups with regard to whether they were admitted directly from theatre (surgical) to ICU or were admitted from A&E or a ward to ICU (non-surgical).

Summary

Patients recruited into the study (n=150) all demonstrated similar demographic and descriptive variables in each of the three patient study groups.

4.2.2.2 Data Set A

A total of 105 (70%) patients from the whole sample received the first intervention on day two of their stay in ICU and were therefore eligible for inclusion in data set A (refer to section 4.1.1; 209-211). Table 4.8.

Table 4.8 Patients eligible for study in data set A

DATA SET A n = 105 (70% of whole data set)	
Control	n = 32 (31%)
Massage only	n = 41 (38%)
Aromatherapy massage	n = 32 (31%)

Age

The mean age of patients recruited to data set A was 62 years (SD 14.6, range 21 to 87 years). The mean age of patients in the control group was 60 years (SD 16, range 21 to 80 years); the mean age of patients in the massage only group was 64 years (SD 13.8, range 31 to 87 years) and the mean age of patients in the aromatherapy massage group was 63 years (SD 14.6, range 24 to 81 years). There were no statistically significant differences between the three subgroups in terms of age.

Table 4.8.1 Ages of patients in data set A by group: values are expressed as Mean (SD)

	Control (n=32)	Massage only (n=41)	Aromatherapy Massage (n=32)	Total (n=105)
Mean age in years (SD)	60 (16)	64 (13.8)	63 (14.6)	62 (14.6)
Range	21 - 80	31 - 87	24 - 81	21 - 87

Social Class

The information obtained regarding the current employment of patients related to 78 (74%) patients. There were 27 (26%) missing cases. The majority of patients (n = 45, 58%) belonged to social class IV, whilst the fewest number of patients were in social class I (n=6, 8%), and social class III (n=6, 8%). There was almost equal numbers of patients in social class II (n=11, 14%) and social class V (n=10, 12%). Table 4.8.2. There were no significant differences between the three subgroups with regards to social class (OPCS 1995).

Table 4.8.2 Social class status (OPCS 1995) of patients in data set A by group

Social Class	Control	Massage only	Aromatherapy massage	Total
I	3 (50%)	1 (17%)	2 (34%)	6 (8%)
II	2 (18%)	6 (55%)	3 (27%)	11 (14%)
III	3 (50%)	0	3 (50%)	6 (8%)
IV	15 (34%)	20 (44%)	10 (22%)	45 (58%)
V	3 (30%)	4 (40%)	3 (30%)	10 (12%)
Total	26 (33%)	31 (40%)	21 (27%)	78 (100%)

Life Events

Sixty five (62%) patients or their next of kin completed the social readjustment rating scale indicating the level of stress in their lives over the previous year. The mean life events score of patients recruited to data set A was 151 (SD 80) with a range of 364 (12 - 376). Patients in the control group demonstrated the highest mean score of 177 (SD 84) with a range of 312 (64 - 376) suggesting that this group of patients may have been exposed to a greater number or more severe stressful life events in the year prior to admission. Patients in the massage only group demonstrated the lowest mean score of 133 (SD 77) and the greatest range of scores of 337 (12 - 349). Patients in the aromatherapy massage group had a mean score of 151 (SD 78) and the lowest range of scores, 296 (49 - 345). See table 4.8.3. There were no significant differences between the three groups in terms of the life events score.

Table 4.8.3 Life Events score of patients in data set A by group: values are expressed as Mean (SD)

	Control (n=19)	Massage only (n=25)	Aromatherapy Massage (n=21)	Total (n=65)
Mean life events score (SD)	177 (84)	133 (77)	151 (78)	152 (80)
Range	64 - 376	12 - 349	49 - 345	12 - 376

APACHE 11 Score

The mean APACHE 11 score of patients recruited to data set A was 19 (SD 5.5, range 7 to 33). The mean APACHE 11 score of patients in the control group was 19 (SD 6.6, range 7 to 33 points); the mean APACHE 11 score of patients in the massage only group was 20 (SD 4.9, range 8 to 33 points) and the mean APACHE 11 score of patients in the aromatherapy massage group was 18 (SD 5.2, range 7 to 26 points). Table 4.9.4.

There were no statistically significant differences between the three groups in terms of the APACHE 11 scores. This demonstrated that patients within each group had a similar severity of illness on admission to intensive care.

Table 4.8.4 APACHE 11 Scores of patients in data set A by group: values are expressed as Mean (SD)

	Control (n=32)	Massage only (n=41)	Aromatherapy Massage (n=32)	Total (n=105)
Mean APACHE 11 Scores (SD)	19 (6.6)	20 (4.9)	18 (5.2)	19 (5.5)
Range	7 - 33	8 - 33	7 - 26	7 - 33

Gender

Forty seven (45%) patients eligible for inclusion in data set A were male and 58 (55%) were female. The control group had almost equal proportions of male and female patients, male n=17 (53%), female n=15 (47%); the massage only group also had almost equal proportions of male and female patients, male n=20 (49%), female n=21 (51%); the aromatherapy massage group had more than double the number of female patients, n=22 (69%) compared to male patients, n=10 (31%). Table 4.8.5. There were no significant differences between the three groups in terms of gender.

Table 4.8.5 Gender of patients in data set A by group

	Gender		Total
Group	Male	Female	
Control	17 (53%)	15 (47%)	32
Massage only	20 (49%)	21 (51%)	41
Aromatherapy massage	10 (31%)	22 (69%)	32
Total	47 (45%)	58 (55%)	105

Diagnoses

The largest group of patients had respiratory illnesses (n=48, 46%). There were more patients with respiratory diagnoses in the massage only group n=23 (56%), and aromatherapy massage group n=16 (50%) than in the control group n=9 (28%). Those patients with cardiovascular illnesses (n=28, 27%) and gastrointestinal illnesses (n=27, 26%) also represented a large proportion of patients. Patients with renal disease accounted for only two (1%) patients. Table 4.8.6.

There were no significant differences between the three groups in relation to the diagnoses.

Table 4.8.6 Diagnoses of patients in data set A by group

	DIAGNOSIS				
	Cardio-vascular	Gastro-intestinal	Respiratory	Renal	Total
Control	9 (28%)	13 (41%)	9 (28%)	1 (3%)	32
Massage only	9 (22%)	9 (22%)	23 (56%)	0	41
Aromatherapy massage	10 (31%)	5 (16%)	16 (50%)	1 (3%)	32
Total	28 (27%)	27 (26%)	48 (46%)	2 (1%)	105

Surgical Status

The majority of patients were admitted to ICU from theatre following a surgical procedure (58, 55%) while 47 (45%) patients were admitted from A&E or from a ward. Twenty (63%) patients from the control group, 19 (46%) patients from the massage only group and 19 (59%) patients from the aromatherapy massage group had undergone a surgical procedure immediately prior to ICU admission and were admitted from theatre. Twelve (38%) patients from the control group, 22 (54%) from the massage only group and 13 (41%) from the aromatherapy massage group were admitted from the A&E department or from a ward and had not undergone a surgical procedure immediately prior to ICU admission. Table 4.8.7.

Table 4.8.7 Surgical Status of patients in data set A by group

	Non-surgical	Surgical	Total
Control	12 (38%)	20 (62%)	32
Massage only	22 (54%)	19 (46%)	41
Aromatherapy massage	13 (41%)	19 (59%)	32
Total	47 (45%)	58 (55%)	105

There were no significant differences between the three groups with regard to whether they had undergone surgery immediately prior to ICU admission or not.

Summary of data set A

There were no demographic or descriptive differences between patients recruited to the whole data set and patients in data set A. There were also no significant differences between the three groups of patients in data set A in terms of their demographic and descriptive variables.

4.2.2.3 Data Set B

A total of 32 (21%) patients from the whole sample were included in data set B; control group n=9 (28%), massage only group n=14 (44%), aromatherapy massage group n=9 (28%). Data set B received the intervention on day two and day five of their stay in ICU.

Table 4.9 Patients eligible for study in data set B

DATA SET B n = 32 (21% of whole data set)	
Control	n = 9 (28%)
Massage only	n = 14 (44%)
Aromatherapy massage	n = 9 (28%)

Age

The mean age of patients recruited to data set B was 63 years (SD=13.63, range 26 to 82 years). The mean age of patients for each subgroup was as follows; the mean age of patients was 62 (SD=14.5, range 26 to 77 years) in the control group, 63 (SD=15.5, range 34 to 82 years) in the massage only group and 65 (SD=10.7, range

47 to 77 years) in the aromatherapy massage group. There were no statistically significant differences between the three subgroups in terms of age.

Table 4.9.1 Ages of patients in data set B by group: values are expressed as Mean (SD)

	Control (n=9)	Massage only (n=14)	Aromatherapy Massage (n=9)	Total (n=32)
Age in years (SD)	62 (14.5)	63 (15.5)	65 (10.7)	63 (13.63)
Range	26 - 77	34 - 82	47 - 77	26 - 82

Social Class

The information obtained regarding the current employment of patients relates to 26 (81%) patients. There were 6 (19%) missing cases. The majority of patients (n = 17, 64%) belonged to social class IV, whilst the fewest number of patients were in social class I (n = 1, 4%). There were two (8%) patients in social class III. There were equal numbers of patients in social classes II and V (n=3, 12%). Table 4.9.2.

Table 4.9.2 Social class status (OPCS 1995) of patients in data set B by group

Social Class	Control	Massage only	Aromatherapy massage	Total
I	0	0	1 (100%)	1 (4%)
II	0	3 (100%)	0	3 (12%)
III	1 (50%)	0	1 (50%)	2 (8%)
IV	5 (29%)	7 (42%)	5 (29%)	17 (64%)
V	0	2 (67%)	1 (33%)	3 (12%)
Total	6 (23%)	12 (46%)	8 (31%)	26 (100%)

There were no significant differences between the three subgroups with regards to social class.

Life Events

Twenty four (75%) patients or their next of kin completed the social readjustment rating scale indicating the level of stress in their lives over the previous year. The mean life events score of patients recruited to data set B was 144 (SD 70) with a range of 289 (12-301). Patients in the control group demonstrated the highest mean score of 171 (SD 84) with a range of 209 (66-275) suggesting that this group of patients may have been exposed to a greater number or more severe stressful life events in the year prior to admission. Patients in the massage only group demonstrated the lowest mean score of 136 (SD 79) and the greatest range of scores of 289 (12-301). Patients in the aromatherapy massage group had a mean score of 139 (SD 44) and the lowest range of scores 107 (88-195). See table 4.9.3. There were no significant differences between the three groups in terms of the mean life events scores.

Table 4.9.3 Life Events scores of patients in data set B by group: values are expressed as Mean (SD)

	Control (n=5)	Massage only (n=12)	Aromatherapy Massage (n=7)	Total (n=24)
Mean life events score (SD)	171 (84)	137 (79)	139 (44)	145 (70)
Range	66 - 275	12 - 301	88 - 195	12 - 301

APACHE 11 Score

The mean APACHE 11 score of patients recruited to data set B was 19 (SD=6.1, range 10 to 33 points). The mean APACHE 11 score for the control group was 21 (SD = 8.5, range 10 to 33 points), for the massage only group was 19 (SD=5.2, range 13 to 28 points) and was 17 (SD=4.4, range 10 to 22 points) for the aromatherapy massage group. Table 4.9.4. There were no statistically significant differences between the three groups regarding the APACHE 11 scores, indicating that all groups were of a similar severity of illness when admitted to the ICU.

Table 4.9.4 APACHE 11 scores of patients in data set B by group: values are expressed as Mean (SD)

	Control (n=9)	Massage only (n=14)	Aromatherapy Massage (n=9)	Total (n=32)
Mean APACHE 11 scores (SD)	21 (8.5)	19 (5.2)	17 (4.4)	19 (6.1)
Range	10 - 33	13 - 28	10 - 22	10 - 33

Gender

Of the 32 patients allocated into data set B, 14 were male (44%) and 18 were female (56%). When the sample was examined further it was found that all three groups were similar regarding the distribution of patients in relation to their gender. There were 3 (33%) male patients and 6 (67%) female patients in the control group, there were equal numbers of both male and female patients in the massage only group (n=7, 50%) and there were 4 (44%) male patients and 5 (56%) female patients in the aromatherapy massage group. There were no significant differences between the three groups with regards to gender.

Table 4.9.5 Gender of patients in data set B by group

	Gender		Total
Group	Male	Female	
Control	3 (33%)	6 (67%)	9
Massage only	7 (50%)	7 (50%)	14
Aromatherapy massage	4 (44%)	5 (56%)	9
Total	14 (44%)	18 (56%)	32

Diagnoses

Of the 32 patients allocated into data set B, they were identified into three categories of diagnosis (out of a possible nine) using the International Classification of Diseases (1960). These were cardiovascular n=6 (19%), gastrointestinal n=10 (31%) and respiratory n=16 (50%). There were no patients in the renal category. The largest group was represented by respiratory illnesses and accounted for half of all diagnoses.

Although the respiratory diagnosis was the commonest, within the control group it only accounted for two (22%) patients, whilst the gastro-intestinal diagnosis was the largest group (n=5, 56%). There were two (22%) patients with a cardiovascular diagnosis. Within both the massage and aromatherapy massage groups the respiratory diagnosis was the largest group, eight (57%) and six (67%) respectively. The massage group had two (14%) patients with a cardiovascular diagnosis and five (56%) patients with a gastro-intestinal diagnosis. The aromatherapy massage group also had 2 (22%) patients with a cardiovascular diagnosis but only 1 (11%) patient with a gastro-intestinal diagnosis. Table 4.9.6.

Table 4.9.6 Diagnoses of patients in data set B by group

	DIAGNOSIS				Total
	Cardio-vascular	Gastro-intestinal	Respiratory	Renal	
Control	2 (22%)	5 (56%)	2 (22%)	0	9
Massage only	2 (14%)	4 (29%)	8 (57%)	0	14
Aromatherapy massage	2 (22%)	1 (11%)	6 (67%)	0	9
Total	6 (19%)	10 (31%)	16 (50%)	0	32

In relation to their diagnosis on admission to ICU there were no significant differences between the three groups.

Surgical Status

Of the 32 patients recruited to data set B 14 (44%) were admitted from A&E or from a ward and 18 (56%) were admitted from theatre following a surgical procedure. The control group had more than three times the number of surgical patients (n=7, 78%) than non-surgical patients (n=2, 22%), whilst the massage and aromatherapy groups had almost equal numbers of surgical and non-surgical patients. The massage group had eight (57%) non surgical patients and six (43%) surgical patients and the aromatherapy massage group had four (44%) non-surgical patients and five (56%) surgical patients. Table 4.9.7.

Table 4.9.7 Surgical Status of patients in data set B by group

Group	Non-surgical	Surgical	Total
Control	2 (22%)	7 (78%)	9
Massage only	8 (57%)	6 (43%)	14
Aromatherapy massage	4 (44%)	5 (56%)	9
Total	14 (44%)	18 (56%)	32

The numbers of patients recruited to each group showed no significant differences with regard to whether they had undergone surgery immediately prior to ICU admission or not.

Summary of data set B

There were no demographic or descriptive differences between patients recruited to the whole data set and patients in data set B. There were also no significant differences between the three groups of patients in data set B in terms of their demographic and descriptive variables.

4.2.2.4 Summary of section two

There were no significant differences with regards to the demographic and descriptive make up of patients within each data set with regards to their age, APACHE 11 score, gender, diagnosis and surgical status. There were no significant differences between the demographic details of each group used in the analysis. Table 4.10.

Table 4.10 Summary table of significant results of demographic differences between the three experimental groups; control, massage only and aromatherapy massage for each data set.

	Whole Data Set	Data Set A	Data Set B
Age	ns	ns	ns
Social Class	ns	ns	ns
Life Events	ns	ns	ns
APACHE 11	ns	ns	ns
Gender	ns	ns	ns
Diagnosis	ns	ns	ns
Surg/Non surg.	ns	ns	ns

The patient population recruited to the study was representative of the whole patient population recruited to the ICU over the three and a half years of data collection. This suggested that the results would be generalisable to this ICU and other ICUs which admitted similar patients. Results available from the ICU database for the years the study was undertaken for age, APACHE 11 and sex suggest that this study used a representative sample of ICU patients which would make this study generalisable to other ICUs (ICNARC 2000). The results from this study could be adapted to other critical care areas such as high dependency, coronary care and theatre nursing.

4.3 Part Two

4.3.1 Section One: Hypothesis One

Hypothesis: Patients in intensive care receiving massage only or aromatherapy massage will demonstrate a reduction in blood pressure, heart rate and respiratory rate compared to patients receiving no intervention

Data sets A and B were analysed separately. The relationship between the independent variables (groups ie control, massage only and aromatherapy massage) and the dependent variables of systolic blood pressure (SBP), diastolic blood pressure (DBP), heart rate (HR) and respiratory rate (RR) were investigated using repeated measures multivariate analysis of variance (MANOVA), analysis of variance (ANOVA) and means. Any interaction effects were followed up using t-tests. The following multivariate tests were inspected; Pillai's Trace, Wilks' Lambda, Hotelling's Trace and Roy's Largest Root. Interpretation of these four statistics was assisted by reference to Hand and Taylor (1996). MANOVA was chosen as the statistical test to use in this analysis because other statistical methods were not able to analyse all the variables and contrasts in such a comprehensive manner. MANOVA involves analysis of several variables and searches through all the possible sets of variables and all possible contrasts. Variables measured can be either different to each other or can be the same item measured a number of times (repeated measures). Subjects are characterised by their score on several variables. There were three main reasons why MANOVA was selected for use in this study. Firstly, MANOVA was used to help to reduce the chance of concluding that a relationship existed when in fact one may not. Secondly, it was used because the interest of the variables was between combinations of the variables, for example at two different time points. In this study the combination of variables were between four and then eight different time points. Thirdly, it was also used to explore the between-group patterns of differences on a set of variables in total ie the individual variables are of no interest it is their union that is of concern.

Hand and Taylor (1996: pgs 65-68) suggested that there are two main advantages to adopting an approach which is more fundamentally multivariate than the four separate univariate analyses. Firstly as already mentioned, when several tests are conducted there is an increased chance of incorrectly rejecting a null hypothesis. The more tests one does the greater this chance becomes so that we become more and more likely to generate a significant result by chance alone. Multivariate techniques can control this problem. Secondly the information within the data can be used more fully. It could be that a combination of variables is necessary to demonstrate properly the difference between the groups.

DATA SET A

The patient numbers in Data set A were as follows; control n=32, massage only n=41, aromatherapy massage n=32. Repeated measures, multivariate analysis of variance (MANOVA) was initially utilised to determine any differences between the three groups and the four dependent variables over the four time points. Table 4.11.

Table 4.11 MANOVA of hypothesis one, data set A.

Effect		Test	Value	F	Hypothesis df	Sig
Between Subjects	Intercept	Pillai's Trace	0.987	2237.85	4	0
		Wilks' Lambada	0.013	2237.85	4	0
		Hotelling's Trace	78.521	2237.85	4	0
		Roy's Largest Root	78.521	2237.85	4	0
	Group	Pillai's Trace	0.071	1.060	8	0.39
		Wilks' Lambada	0.930	1.054	8	0.40
		Hotelling's Trace	0.074	1.048	8	0.40
		Roy's Largest Root	0.053	1.521	4	0.20
Within Subjects	Time	Pillai's Trace	0.079	0.757	12	0.69
		Wilks' Lambada	0.921	0.757	12	0.69
		Hotelling's Trace	0.086	0.757	12	0.69
		Roy's Largest Root	0.086	0.757	12	0.69
	Time by Group	Pillai's Trace	0.228	1.148	24	0.29
		Wilks' Lambada	0.782	1.156	24	0.29
		Hotelling's Trace	0.266	1.165	24	0.28
		Roy's Largest Root	0.204	1.815	12	0.05

It was found that Roy's Largest Root demonstrated a significance of $p<0.05$ in the within subjects analysis relating to the effect of the interaction, time and group. No other effects were found. Further investigation followed, and the dependent variable respiratory rate (RR) was omitted from the multivariate analysis of variance, as it was demonstrated that there were limited changes within this variable over time (graph 4.5, pg 216). This was due to the respiratory rate mainly being mechanically adjusted (ie by manually changing the ventilator settings, as most patients were mechanically ventilated) and their respiratory rate was not under patient influence.

The multivariate analysis of variance was repeated using the dependent variables of heart rate, systolic blood pressure and diastolic blood pressure. Roy's Largest Root demonstrated an unchanged power of significance ($p<0.05$) in the within subjects analysis relating to time and group. No other variances were found.

However following further reading (Olson 1974, Olson 1976, Olson 1979, Everitt 1998) relating to the validity of Roy's largest root, further analysis was required to establish whether the p values were statistically valid as no other significant results were demonstrated in the other tests of multivariate analysis of variance. According to Olson (1974) Roy's largest root is the least reliable test in multivariate analysis of variance and therefore these results must be read with great caution.

Statistical advice was sought regarding the interpretation of these results. It was suggested that the analysis did not demonstrate any significant results using MANOVA. However, further work could have been undertaken with regards to the MANOVA in the form of plotting all the data for each case, by plotting each case for heart rate, systolic blood pressure and diastolic blood pressure and determining any trends. Any cases that did not fit the general trend would then be excluded from the analysis. Hand and Taylor (1996) highlighted the problem of MANOVA being sensitive to outlying or extreme observations and suggested that data should be checked prior to analysis and any outliers removed. The MANOVA would then be rerun to search for any significance. However after examining the group means which had been plotted, statistical advice suggested that it would be a lengthy procedure to 'employ omission of outliers' which would probably have nothing conclusive to add to the results. The reasons not employing omission of outliers, included, lack of numbers, observation of univariate means and the statistics already show no effects getting close to 5% level therefore a new more detailed analysis would not add clarity or additional information to the analysis

The group means (SD) for each of the four dependent variables are presented for each of the four time points ie immediately pre massage (first recording), immediately post massage (second recording), one hour post massage (third recording) and four hours post massage (fourth recording) for the first intervention on day two of the patients stay in ICU. Univariate analysis of variance (ANOVA) was used to determine any statistical difference between the groups at each time point.

Heart Rate

The mean heart rate for the control group increased slightly over time from 97 (SD 22.2) bpm (beats per minute), first recording, to 97 (SD 17.2) bpm, second recording, to 101 (SD 19.2) bpm, third recording and finally to 102 (SD 20.1) bpm at the fourth recording. Table 4.12.

The mean heart rate for patients in the massage only group changed by one heart beat per minute over the intervention period which could be regarded as negligible and therefore could be stated that the heart rate did not change in the massage group over time. The mean heart rate changed from 98 (SD 17) bpm, first recording, to 97 (SD 18.7) bpm, second recording, to 98 (SD 18.3) bpm, third recording and finally to 97 (SD 15.6) bpm at the fourth recording. Table 4.12.

The mean heart rate for patients in the aromatherapy massage group remained the same until four hours after the intervention when it increased by three beats per minute. The mean heart rate remained static for the first three recordings, 93 (SD 18.5) bpm, first recording, 93 (SD 17.6) bpm, second recording, 93 (SD 16.4) bpm, third recording and then finally increased to 96 (SD 19.9) bpm at the fourth recording. Table 4.12.

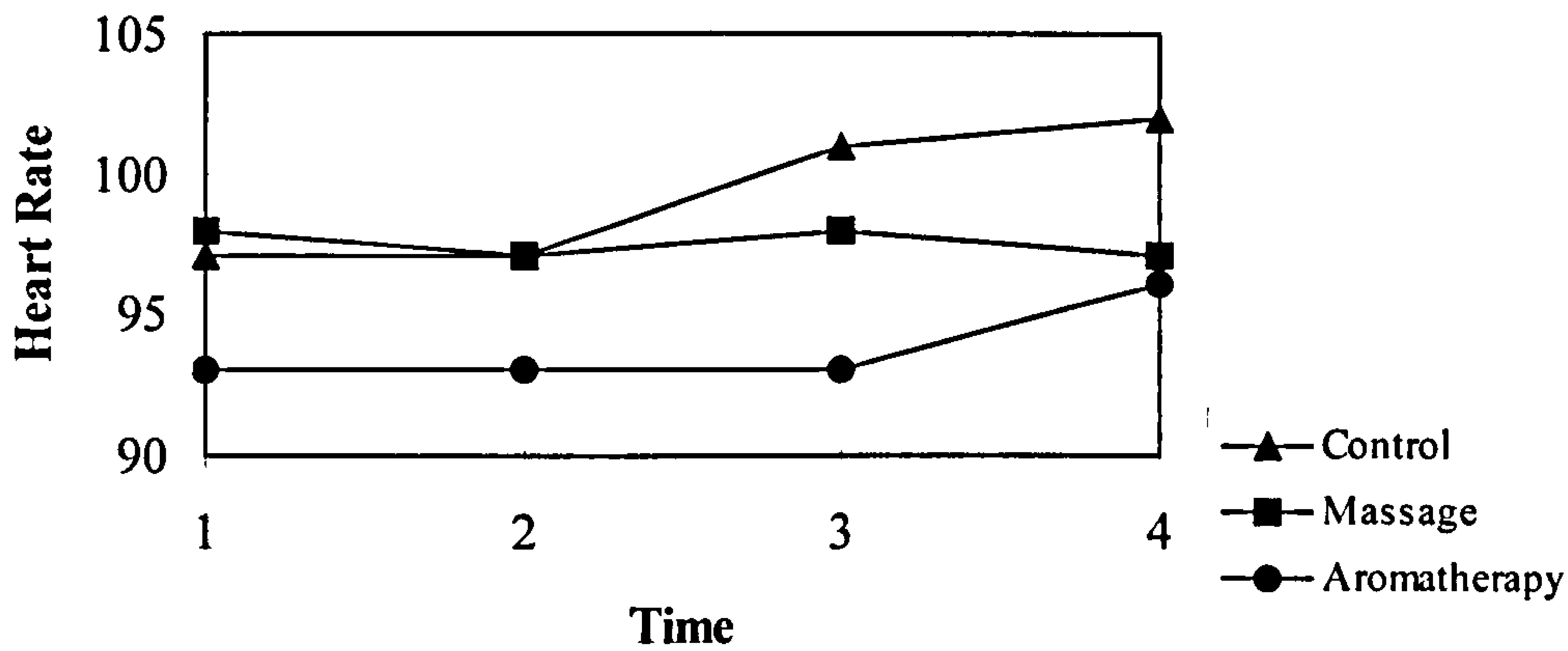
Table 4.12 Mean heart rate (bpm) and standard deviation (SD) by group and time for data set A

Group	1st recording pre-intervention	2nd recording immediately post intervention	3rd recording 1 hour post intervention	4th recording 4 hours post intervention	Sig.
Control (n=32)	97 (22.2)	97 (17.2)	101 (19.2)	102 (20.1)	ns
Massage only (n=41)	98 (17)	97 (18.7)	98 (18.3)	97 (15.6)	ns
Aromatherapy massage (n=32)	93 (18.5)	93 (17.6)	93 (16.4)	96 (19.9)	ns
Significance	ns	ns	ns	ns	

There was little change in the mean heart rate over time for patients in all three of the patient groups. No significant differences were found between or within the three groups in relation to mean heart rate over time.

Graph 4.2 clearly shows these minor fluctuations in heart rate. It can be seen that patients in both the control and the aromatherapy massage groups had a slight increase in heart rate, whilst patients in the massage only group demonstrated a slight decrease in heart rate. The changes in heart rate described have no clinical or experimental significance due to the very small fluctuations (ie a maximum of only six beats per minute), which would be classed as negligible due to these changes exerting no clinical effects on the patients.

Graph 4.2 Mean heart rate by group and time for data set A



Systolic blood pressure

The mean systolic blood pressure for patients in the control group changed over time from; 139 mmHg (SD 25) first recording, 137 mmHg (SD 24.1) second recording, 137 mmHg (SD 22.4) third recording to 138 mmHg (SD 23.4) at the fourth recording. The mean systolic blood pressure for patients in the massage only group changed over time from; 137 mmHg (SD 26) first recording, 132 mmHg (SD 23.4) second recording, 136 mmHg (SD 26.8) third recording to 137 mmHg (SD 32.7) at the fourth recording. The mean systolic blood pressure for patients in the aromatherapy massage group changed over time from 135 mmHg (SD 23.6) first recording, 138 mmHg (SD 22.2) second recording, 137 mmHg (SD 23.3) third recording to 138 mmHg (SD 27) at the fourth recording. Table 4.13.

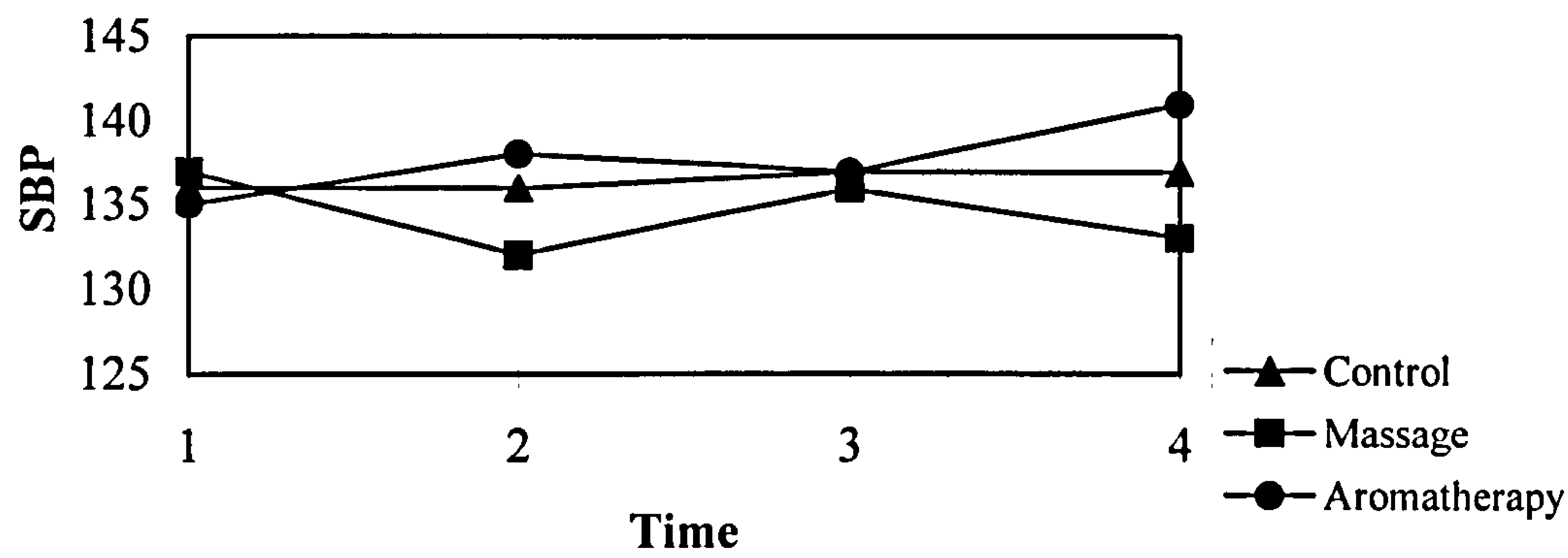
Table 4.13 Mean systolic blood pressure (mmHg) and standard deviation (SD) by group and time for data set A

Group	1st recording pre-intervention	2nd recording immediately post intervention	3rd recording 1 hour post intervention	4th recording 4 hours post intervention	Sig.
Control (n=32)	139 (25)	137 (24.1)	137 (22.4)	138 (23.4)	ns
Massage only (n=41)	137 (26)	132 (23.4)	136 (26.8)	137 (32.7)	ns
Aromatherapy massage (n=32)	135 (23.6)	138 (22.2)	137 (23.3)	138 (27)	ns
Significance	ns	ns	ns	ns	

No significant differences were found between or within the three groups of patients in respect of mean systolic blood pressure over time.

Graph 4.3 clearly shows the minor fluctuations in mean systolic blood pressure for each group over time. The graph shows that patients in the control group did not demonstrate a change in mean blood pressure over time, whilst patients in the massage only group demonstrated a slight reduction in mean blood pressure over time. Patients in the aromatherapy massage group demonstrated a slight increase in mean blood pressure over time. There were subtle changes in the mean systolic blood pressure of patients in each of the experimental groups but these changes had no clinical effect on the patients' condition or health due to their small change. Graph 4.3.

Graph 4.3. Mean systolic blood pressure by group and time for data set A



Diastolic blood pressure

The mean diastolic blood pressure for patients in the control group changed over time from; 63 mmHg (SD 13) first recording, 64 mmHg (SD 10.5) second recording, 62 mmHg (SD 12) third recording to 65 mmHg (SD 13.4) at the fourth recording. The mean diastolic blood pressure for patients in the massage only group changed over time from; 62 mmHg (SD 11.1) first recording, 61 mmHg (SD 10.4) second recording, 61 mmHg (SD 11.8) third recording to 60 mmHg (SD 11.6) at the fourth recording. Finally the mean diastolic blood pressure for patients in the aromatherapy massage group changed over time from 62 mmHg (SD 11.7) first recording, 63 mmHg (SD 12.2) second recording, 62 mmHg (SD 12.1) third recording to 63 mmHg (SD 11.5) at the fourth recording. Table 4.14.

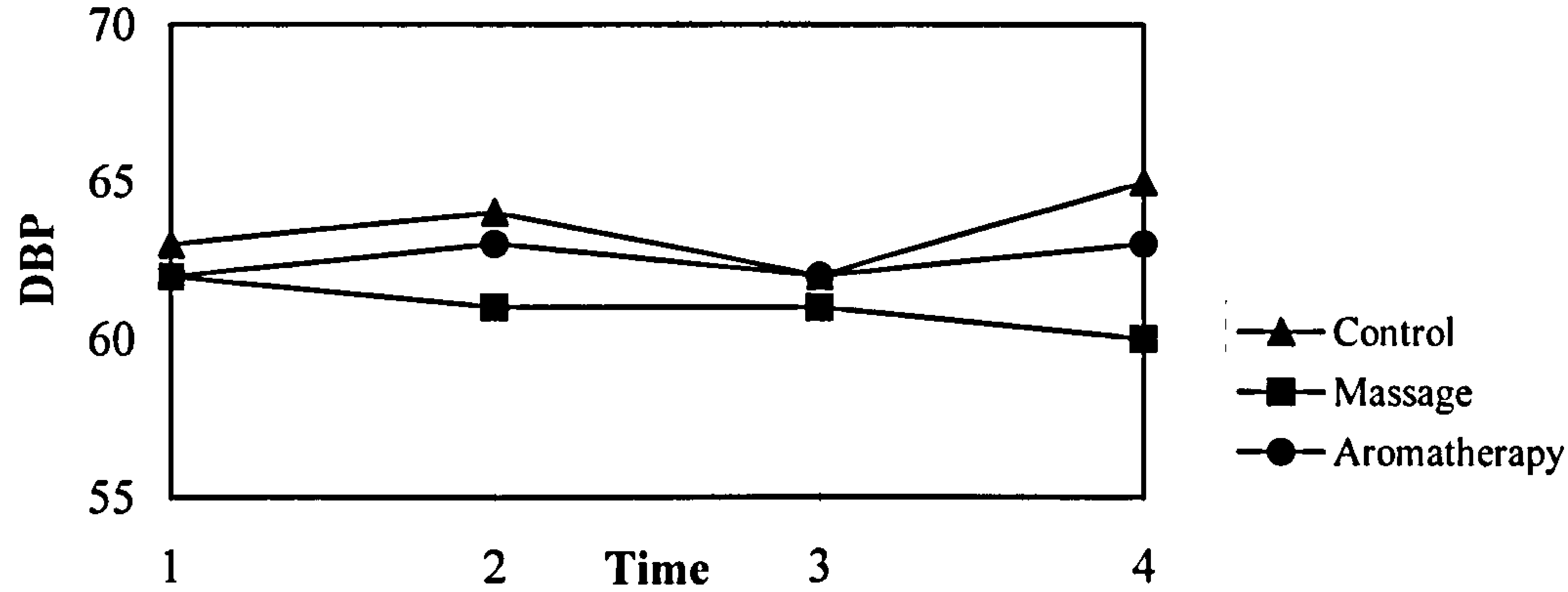
Table 4.14 Mean diastolic blood pressure (mmHg) and standard deviation (SD) by group and time for data set A

Group	1st recording pre-intervention	2nd recording immediately post intervention	3rd recording 1 hour post intervention	4th recording 4 hours post intervention	Sig.
Control (n=32)	63 (13)	64 (10.5)	62 (12)	65 (13.4)	ns
Massage only (n=41)	62 (11.1)	61 (10.4)	61 (11.8)	60 (11.6)	ns
Aromatherapy massage (n=32)	62 (11.7)	63 (12.2)	62 (12.1)	63 (11.5)	ns
Significance	ns	ns	ns	ns	

No significant differences were found between or within the three groups of patients in respect of their mean diastolic blood pressure and massage over time.

Graph 4.4 clearly shows the negligible fluctuations in mean diastolic blood pressure for patients in each group over time. Graph 4.4 shows that patients in the aromatherapy massage group did not demonstrate a change in diastolic pressure over time, whilst patients in the control group showed a slight increase in diastolic blood pressure over time and patients in the massage only group demonstrated a slight decrease in diastolic blood pressure over time. There were subtle changes in mean diastolic blood pressure for patients in each of the experimental groups but these changes demonstrated no clinical meaning to a patients' condition or health.

Graph 4.4 Mean diastolic blood pressure by group and time for data set A



Respiratory Rate

The mean respiratory rate per minute for patients in the control group changed from 14 respirations per minute (rpm) (SD 4.67) at the first recording to 15 rpm for the following three recordings; 15 rpm (SD 5.19) second recording, 15 rpm (SD 1.41) third recording, 15 rpm (SD 5.12) fourth recording. The mean respiratory rate for patients in the massage only group changed from 16 rpm (SD 7.44) first recording, 16 rpm (SD 8.77) second recording, 17 rpm (SD 8.47) third recording and then returned to 16 rpm (SD 7.32) at the fourth recording. Finally the mean respiratory rate per minute for patients in the aromatherapy massage group remained at 14 rpm for the first three recordings; (SD 4.56) first recording, 14 rpm (SD 6.04) second recording, 14 rpm (SD 5.53) third recording and then increased to 15 rpm (SD 6.25) for the fourth recording. Table 4.15.

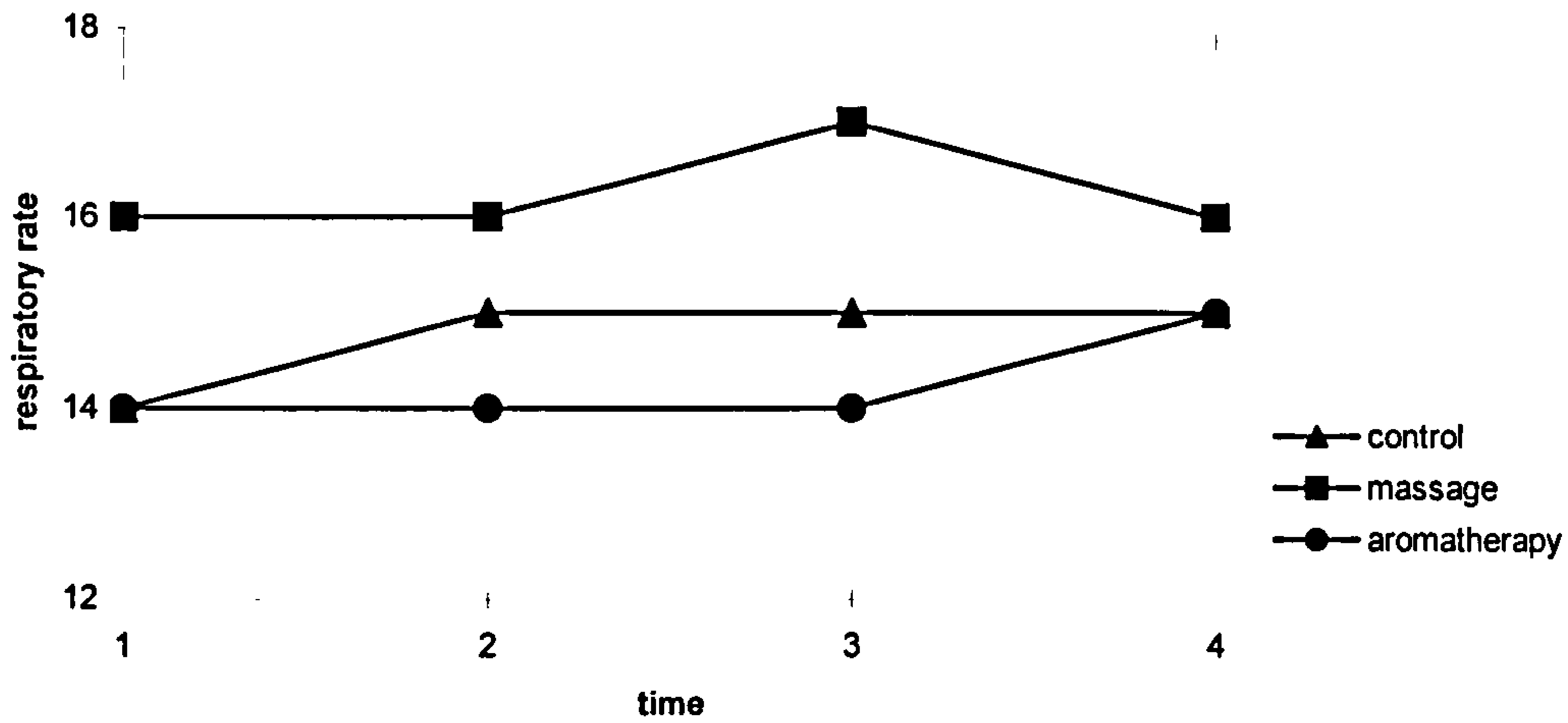
Table 4.15 Mean respiratory rate (rpm) and standard deviation (SD) by group and time for data set A

Group	1st recording pre-intervention	2nd recording immediately post intervention	3rd recording 1 hour post intervention	4th recording 4 hours post intervention	Sig.
Control (n=32)	14 (4.67)	15 (5.19)	15 (1.41)	15 (5.12)	ns
Massage only (n=41)	16 (7.44)	16 (8.77)	17 (8.47)	16 (7.32)	ns
Aromatherapy massage (n=32)	14 (4.56)	14 (6.04)	14 (5.53)	15 (6.25)	ns
Significance	ns	ns	ns	ns	

No significant differences were found between the three groups of patients in respect of their mean respiratory rate per minute over time.

Graph 4.5 clearly shows the limited fluctuation in the mean respiratory rate for each group of patients over time. Patients in the control and aromatherapy massage groups demonstrated an increase of one breath per minute over time. Patients in the massage only group demonstrated a slight fluctuation in mean respiratory rate during the time period, but respiratory rate returned to the baseline figure over time. There were very subtle changes in mean respiratory rate of patients in each of the experimental groups but these changes elicited no clinical meaning to patient's condition or health.

Graph 4.5. Mean respiratory rate by group and time for data set A



The effects of using artificial respiration gives a regular number of respirations each minute and therefore do not produce fluctuations in the same manner as natural respirations. Little change is demonstrated over time between the patients in the three groups due to the large numbers of patients who were ventilated (n=85, 80%).

DATA SET B

The group means (SD) for each of the dependent variables are presented for each time point for the first intervention and second intervention. The independent variable of respiratory rate per minute was excluded from the analysis based on the multivariate analysis of variance findings for data set A, which demonstrated that due to the limited fluctuation in this variable it did not contribute to the analysis.

Multivariate analysis of variance (MANOVA) was initially utilised to determine any differences between the three groups over the four time points. There were no statistical differences between or within the three groups over time.

Univariate analysis of variance (ANOVA) was used to determine any statistical difference between the groups at each time point.

Heart Rate

As shown in table 4.16 the mean heart rate per minute for the control group changed over time from; 104 beats per minute (b.p.m.) (SD 28.93) first recording, 100 b.p.m. (SD 15.02) second recording, 103 b.p.m. (SD 17.5) third recording to 94 b.p.m. (SD 19.13) fourth recording, 100 b.p.m. (SD 21.66) fifth recording, 97 b.p.m. (SD 17.64) sixth recording, 94 b.p.m. (SD 21.9) seventh recording to 96 b.p.m. (SD 20.44) at the eighth recording.

The mean heart rate per minute for the massage only group changed over time from; 97 b.p.m. (SD 15.09) first recording, 96 b.p.m. (SD 15.58) second recording, 96 b.p.m. (SD 18.05) third recording to 96 b.p.m. (SD 15.01) fourth recording, 92 b.p.m. (SD 15.95) fifth recording, 97 b.p.m. (SD 15.59) sixth recording, 93 b.p.m. (SD 16.06) seventh recording to 95 b.p.m. (SD 18.22) at the eighth recording. Table 4.16.

The mean heart rate for the aromatherapy massage group changed over time from 86 b.p.m. (SD 21.67) first recording, 88 b.p.m. (SD 18.82) second recording, 87 b.p.m. (SD 14.93) third recording to 83 b.p.m. (SD 17.14) fourth recording, 96 b.p.m. (SD 25.97) fifth recording, 94 b.p.m. (SD 25.9) sixth recording, 87 b.p.m. (SD 18.89) seventh recording to 93 b.p.m. (SD 37.82) at the eighth recording. Table 4.16.

Table 4.16 Mean (SD) heart rate (bpm) and standard deviation (SD) by group and time for data set B

	Control (n=9)	Massage only (n=14)	Aromatherapy massage (n=9)
First Intervention			
1st recording immediately pre intervention	104 (28.93)	97 (15.09)	86 (21.67)
2nd recording immediately post intervention	100 (15.02)	96 (15.58)	88 (18.82)
3rd recording 1 hour post intervention	103 (17.5)	96 (18.05)	87 (14.93)
4th recording 4 hours post intervention	94 (19.13)	96 (15.01)	83 (17.14)
Second Intervention			
5th recording immediately pre intervention	100 (21.66)	92 (15.95)	96 (25.97)
6th recording immediately post intervention	97 (17.64)	97 (15.59)	94 (25.9)
7th recording 1 hour post intervention	94 (21.9)	93 (16.06)	87 (18.89)
8th recording 4 hours post intervention	96 (20.44)	95 (18.22)	93 (37.82)

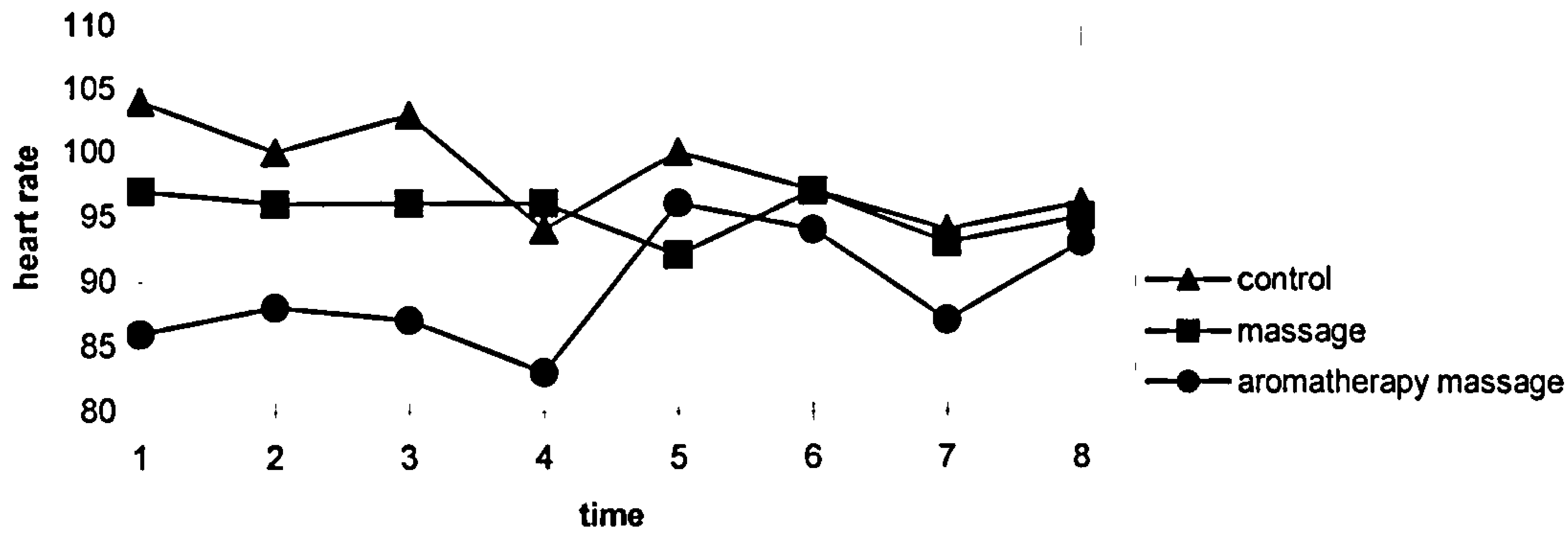
No significant differences were found within or between the three groups of patients in respect of their mean heart rate per minute over time.

The heart rate per minute fluctuated over time in all three patient groups. The mean heart rate for all patient groups appeared to demonstrate a slight downward trend over time. There is no difference between the three groups in relation to mean heart rate and massage only or aromatherapy massage.

Systolic Blood Pressure

As shown in table 4.17 the mean systolic blood pressure for patients in the control group changed over time from; 148 mmHg (SD 28.63) first recording, 137 mmHg (SD 20.65) second recording, 135 mmHg (SD 22.09) third recording to 144 mmHg (SD 21.88) fourth recording, 138 mmHg (SD 21.61) fifth recording, 146 mmHg (SD 17.2) sixth recording, 138 mmHg (SD 18.56) seventh recording to 150 mmHg (SD 20.01) at the eighth recording.

Graph 4.6 Mean heart rate by group and time for data set B



The mean systolic blood pressure for patients in the massage only group changed over time from; 144 mmHg (SD 27.54) first recording, 142 mmHg (SD 22.93) second recording, 140 mmHg (SD 28.8) third recording to 149 mmHg (SD 37.93) fourth recording, 156 mmHg (SD 33.91) fifth recording, 152 mmHg (SD 33.48) sixth recording, 147 mmHg (SD 29.37) seventh recording to 147 mmHg (SD 21.91) at the eighth recording. Table 4.17.

The mean systolic blood pressure for patients in the aromatherapy massage group changed over time from 135 mmHg (SD 19.57) first recording, 140 mmHg (SD 17.71) second recording, 139 mmHg (SD 18.65) third recording to 137 mmHg (SD 16.34) fourth recording, 140 mmHg (SD 33.39) fifth recording, 149 mmHg (SD 27.56) sixth recording, 158 mmHg (SD 31.14) seventh recording to 142 mmHg (SD 29.48) at the eighth recording. Table 4.17.

Table 4.17 Mean systolic blood pressure (mmHg) and standard deviation (SD) by group and time for data set B.

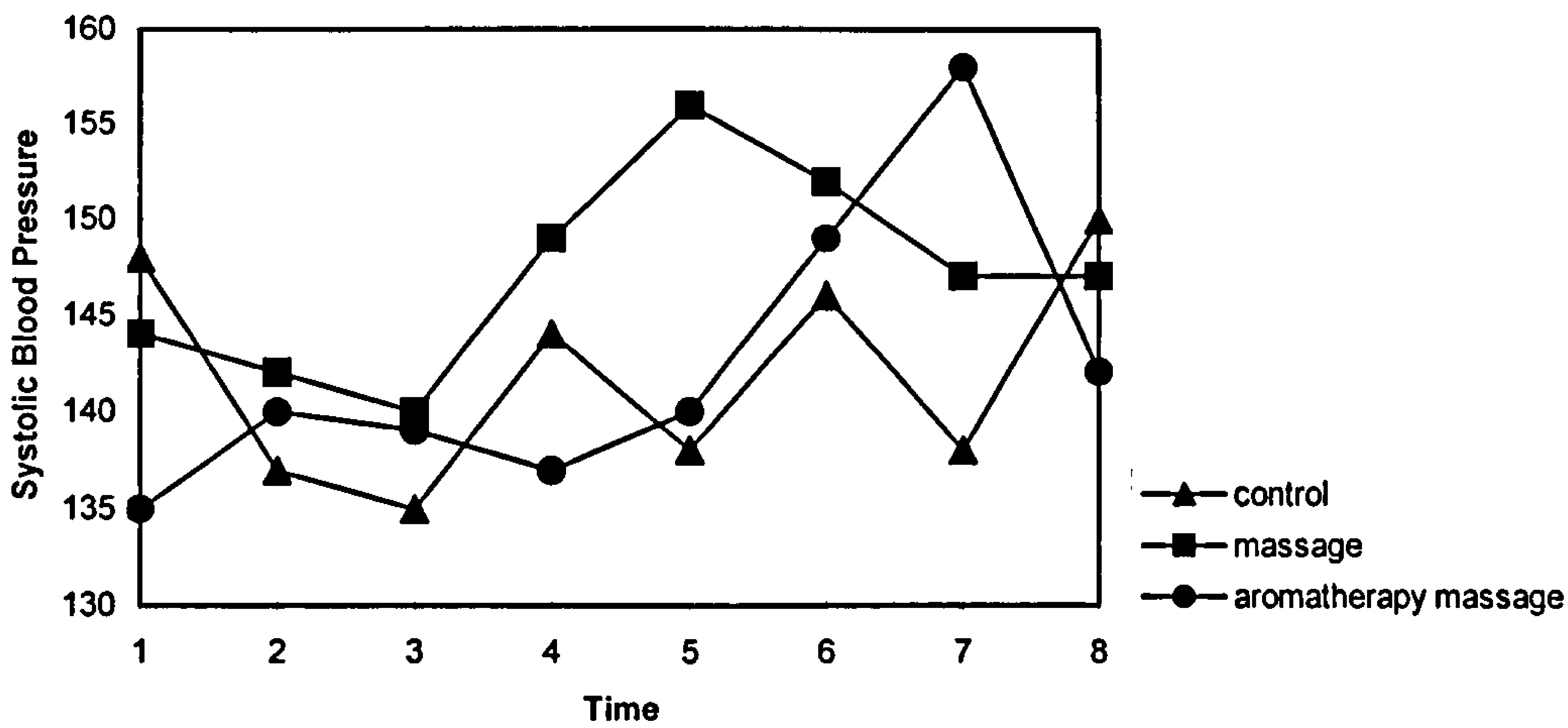
	Control (n=9)	Massage only (n=14)	Aromatherapy massage (n=9)
First Intervention			
1st recording immediately pre intervention	148 (28.63)	144 (27.54)	135 (19.57)
2nd recording immediately post intervention	137 (20.65)	142 (22.93)	140 (17.71)
3rd recording 1 hour post intervention	135 (22.09)	140 (28.8)	139 (18.65)
4th recording 4 hours post intervention	144 (21.88)	149 (37.93)	137 (16.34)
Second Intervention			
5th recording immediately pre intervention	138 (21.61)	156 (33.91)	140 (33.39)
6th recording immediately post intervention	146 (17.2)	152 (33.48)	149 (27.56)
7th recording 1 hour post intervention	138 (18.56)	147 (29.37)	158 (31.14)
8th recording 4 hours post intervention	150 (20.01)	147 (21.91)	142 (29.48)

The mean systolic blood pressure in all three groups of patients fluctuated over time. The systolic blood pressure for patients in the control group declined immediately following the first massage but increased immediately following the second massage. The systolic blood pressure for patients in the massage group reduced immediately following both of the massages and had returned to the baseline at time point eight. Patients who received aromatherapy massage demonstrated an increase in systolic blood pressure following both of the massages and it remained slightly higher than at baseline.

No significant differences were found between patients in the three groups in respect of their mean systolic blood pressure over time.

Graph 4.7 clearly demonstrates the fluctuations in the mean systolic blood pressure over time and shows that there are no trends in any of the patient groups.

Graph 4.7 Mean systolic blood pressure by group and time for data set B



Diastolic Blood Pressure

The mean diastolic blood pressure for patients in the control group changed over time from; 66 mmHg (SD 14.08) first recording, 67 mmHg (SD 13.22) second recording, 60 mmHg (SD 12.94) third recording to 68 mmHg (SD 17.75) fourth recording, 67 mmHg (SD 18.67) fifth recording, 69 mmHg (SD 18.92) sixth recording, 69 mmHg (SD 18.26) seventh recording to 73 mmHg (SD 16.86) at the eighth recording. Table 4.18.

The mean diastolic blood pressure for patients in the massage only group changed over time from; 62 mmHg (SD 8.91) first recording, 60 mmHg (SD 8.02) second recording, 58 mmHg (SD 12.09) third recording to 61 mmHg (SD 14.26) fourth recording, 63 mmHg (SD 14.4) fifth recording, 62 mmHg (SD 13.34) sixth recording, 60 mmHg (SD 11.56) seventh recording to 64 mmHg (SD 10.33) at the eighth recording. Table 4.18.

The mean diastolic blood pressure for patients in the aromatherapy massage group changed over time from 60 mmHg (SD 10.44) first recording, 60 mmHg (SD 10.91) second recording, 59 mmHg (SD 8.63) third recording to 62 mmHg (SD 11.6) fourth recording, 64 mmHg (SD 16.33) fifth recording, 64 mmHg (SD 15.52) sixth recording, 69 mmHg (SD 15.16) seventh recording to 59 mmHg (SD 6.69) at the eighth recording. Table 4.18.

Table 4.18 Mean diastolic blood pressure (mmHg) and standard deviation (SD) by group and time for data set B

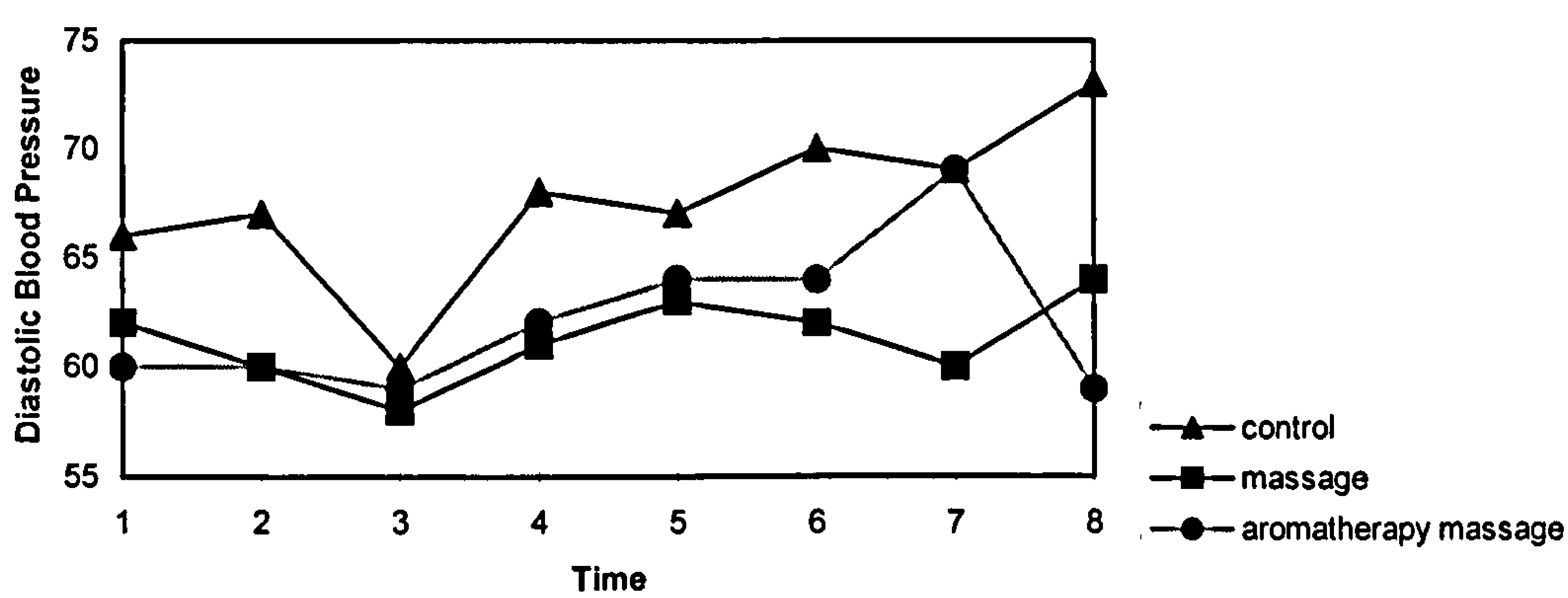
	Control (n=9)	Massage only (n=14)	Aromatherapy massage (n=9)
First Intervention			
1st recording immediately pre intervention	66 (14.08)	62 (8.91)	60 (10.44)
2nd recording immediately post intervention	67 (13.22)	60 (8.02)	60 (10.91)
3rd recording 1 hour post intervention	60 (12.94)	58 (12.09)	59 (8.63)
4th recording 4 hours post intervention	68 (17.75)	61 (14.26)	62 (11.6)
Second Intervention			
5th recording immediately pre intervention	67 (18.67)	63 (14.4)	64 (16.33)
6th recording immediately post intervention	69 (18.92)	62 (13.34)	64 (15.52)
7th recording 1 hour post intervention	69 (18.62)	60 (11.56)	69 (15.16)
8th recording 4 hours post intervention *	73 (16.86)	64 (10.33)	59 (6.69)

* $p<0.05$

There was one significant result for diastolic blood pressure over time between the three groups and this was at the eighth diastolic blood pressure ie the diastolic blood pressure which was recorded four hours after the second intervention; $F(2,28)=3.37$; $p=0.049$ (Table 4.18). Further investigation of this finding demonstrated that there was a significant result between the control group and the aromatherapy group for mean diastolic blood pressure at fours hours following the second intervention; $t=2.41$, $df=15$, $p=0.035$. Patients in the aromatherapy massage group demonstrated a significantly reduced diastolic blood pressure four hours after the second intervention. The mean diastolic blood pressure was also lower than those patients in the massage only group. These results are indicative that following two aromatherapy massages, patients are beginning to demonstrate changes in diastolic blood pressure suggestive of relaxation, compared to patients who received no aromatherapy massage and did not demonstrate significant reductions in mean diastolic blood pressure.

Graph 4.8 clearly demonstrates the fluctuations in diastolic blood pressure and the general trends relating to each patient group. All patient groups appear to mirror each others mean diastolic blood pressure over the first seven recordings. At time point eight, four hours following the second aromatherapy massage, patients in this group demonstrated a significant reduction in mean diastolic blood pressure.

Graph 4.8 Mean diastolic blood pressure by group and time for data set B



Summary

A summary of all the significant results for hypothesis one (data sets A and B) have been included in table 4.19.

Table 4.19 Summary table of significant results for hypothesis one

DATA SET	Statistical test	Heart rate	Systolic blood Pressure	Diastolic blood pressure	Respiratory rate
A	MANOVA			ns	
	ANOVA	ns	ns	ns	ns
B	MANOVA			ns	
	ANOVA	ns	ns	P<0.05	ns

There was one significant finding in hypothesis one, relating to diastolic blood pressure four hours following the second intervention. There was a significant difference in the diastolic blood pressure between patients in the control group and patients who had received an aromatherapy massage. Patients who had received an aromatherapy massage showed a reduction in mean diastolic blood pressure (59mmHg) compared to those patients in the control group (73mmHg). Patients who had received massage only also demonstrated a reduction in mean diastolic blood pressure (64mmHg) compared to patients in the control group (73mmHg), although this was not significant.

The null hypothesis is accepted for patients who received one massage, but in those patients who received two consecutive massages the null hypothesis for diastolic blood pressure is rejected. The null hypothesis is accepted in all other physiological variables.

None of the studies examining the effects of aromatherapy massage were able to demonstrate any significant changes in heart rate. Five studies (Fakouri and Jones 1987, Field et al 1992, Meek 1993, Field et al 1998, Hayes and Cox 2000) using massage only did demonstrate significant reductions in heart rate. It is unclear as to why the differences between massage only and aromatherapy massage studies have occurred. One explanation may be that results are overlooked in the aromatherapy massage studies because they are attempting to demonstrate an effect with essential oils.

4.3.2 Section Two: Hypothesis Two

Hypothesis: Patients in intensive care receiving massage only or aromatherapy massage will require less analgesia than those not receiving massage only or aromatherapy massage

Patients were prescribed one or more analgesic drugs, which included intravenous morphine, intravenous alfentanil or bupivacaine hydrochloride as an epidural. These were administered to patients in differing combinations and doses during their stay in ICU.

A panel of experienced colleagues assisted with the analysis of this data and levels of analgesic drugs administered on a daily basis were categorised into levels of none or minimal, moderate amounts or high amounts. Few patients were assigned to the high amounts category and therefore this category was merged into the moderate category and gave two categories (none or minimal and moderate to high).

These data were then used in the analysis and chi-square and logistical regression were applied. Days one to four were selected as the days to analyse the quantity of drugs received by patients for the first intervention. This was so that the quantity of analgesic drugs given prior to the intervention and the quantity of analgesic drugs received following the intervention could be taken into consideration, up until the second intervention ie day five.

The level of pain experienced by patients was also measured using the newly developed pain chart (appendix 6) and these scores were analysed to determine any differences between the three groups of patients with regard to their pain levels.

Table 4.20 Numbers of patients in data set A receiving analgesic drugs over the first four days of their stay in ICU

Experimental Group		Control	Massage only	Aromatherapy massage	Total
Data set A		32 (31%)	41 (38%)	32 (31%)	105 (100%)
Numbers of Patients Receiving Analgesic drugs	morphine	19 (58%)	24 (55%)	14 (41%)	57 (53%)
	diamorphine	6 (18%)	6 (12%)	3 (9%)	15 (12%)
	alfentanil	2 (6%)	4 (8%)	13 (41%)	19 (17%)
	none	6 (18%)	11 (25%)	3 (9%)	20 (18%)

4.3.2.1 Data Set A

4.3.2.1.1 Quantity of analgesic drugs received

The majority of patients received analgesia in, the none to minimal level, over the first four days of their stay in ICU. On day one the majority of patients were categorised in the analgesia grouping, none to minimal (n=94, 90%). This may have been because patients had not been in ICU for a full twenty-four hours of that day and therefore received less analgesia. On days two and three the same numbers of patients received the same amounts of none to minimal levels of analgesia (n=86, 82%) and moderate to high levels of analgesia (n=19, 18%). On day four there were more patients who received none to minimal analgesia (n=92, 88%). This was expected as patients reduce their levels of analgesia as they recover from a critical illness. Patients who become more ill will increase their levels of analgesia.

On day one, the same percentage of patients in the control group and massage only group received the same levels of analgesia. Eighty eight percent of patients received, none to minimal analgesia, whilst twelve percent received moderate to high. This contrasts with those patients in the aromatherapy massage group as only six percent received analgesia in the level of moderate to high category.

Patients' utilisation of analgesia was similar over days two and three. Patients in the control group used more sedation than patients in the massage group, who used more sedation than those patients in the aromatherapy group. On both days the percentage of patients in the aromatherapy massage group that were categorised as using moderate to high levels of analgesia (9%) was almost half that of patients in the massage only group (17%). The percentage of patients in the aromatherapy massage group that were categorised as using moderate to high levels of analgesia (9%) was more than a third less than those patients in the control group (31%). This suggests that patients who received a massage only required a reduced level of moderate to high analgesia compared to patients in the control group and that patients' benefit further from the use of essential oil in the massage by demonstrating a greater reduction of moderate to high level analgesia.

On day four patients who received massage only or aromatherapy massage demonstrated similar usage of analgesia. Patients in the control group were still utilising more analgesia in the moderate to high category. When the level of analgesia was compared on day one (prior to any intervention) with the levels of analgesia received following the intervention, there were significant differences between the patients in the control group and patients in the aromatherapy massage group, between day one and day three in the quantity of analgesic drugs utilised (p>0.05). Patients in the aromatherapy massage group used significantly less analgesia on day three, whilst patients in the control group required more analgesia (table 4.21). No other significant differences were found.

Table 4.21 Numbers of patients and level of analgesia received on days one to four

Day	Level of analgesia	Control (n = 32)	Massage only (n = 41)	Aromatherapy massage (n = 32)	Total (n = 105)
1	None to minimal	28 (88%)	36 (88%)	30 (94%)	94 (90%)
	Moderate to high	4 (12%)	5 (12%)	2 (6%)	11 (10%)
2	None to minimal	23 (72%)	34 (83%)	29 (91%)	86 (82%)
	Moderate to high	9 (28%)	7 (17%)	3 (9%)	19 (18%)
3	None to minimal	22 (69%)	35 (85%)	29 (91%)	86 (82%)
	Moderate to high	10 (31%)	6 (15%)	3 (9%)	19 (18%)
4	None to minimal	25 (78%)	38 (93%)	29 (91%)	92 (88%)
	Moderate to high	7 (12%)	3 (7%)	3 (9%)	13 (12%)

4.3.2.1.2 Pain scores

The mean pain scores showed little change between the three groups over the time of the first intervention. Using ANOVA, there were no significant differences between the three groups and the level of pain recorded.

4.3.2.2 Data Set B

Due to the small sample size of data set B no further analysis was undertaken, as false levels of significance may have resulted in type 11 errors (Whitney 1999).

4.3.2.3 Summary of section two

Patients who received massage only or aromatherapy massage utilised less analgesia than those patients who received no intervention. Patients who received aromatherapy massage utilised less analgesia than those patients in the massage only and control groups on the two days following the intervention. The amount of analgesia used between the groups was significant between patients in the control group and patients in the aromatherapy massage group on days one and three of the study ($p<0.05$).

To examine these results more closely the surgical status of the three groups of patients who had received morphine were examined to determine if this could account for the differences in the analgesia utilised. The control group had five (26%) non surgical patients and nearly three times the number of surgical patients (n=14, 74%). A higher proportion of patients in the aromatherapy massage group were admitted following surgery immediately prior to ICU admission (n=12, 86%) compared to being admitted from A&E or from the wards (n=2, 14%). Patients in the massage only group were distributed almost equally between those who had received surgery immediately prior to ICU admission (n=14, 58%) and those who had not patients (n=10, 42%). All three groups had similar numbers of surgical patients. There were no significant differences between the three groups with regards to whether they had undergone surgery immediately prior to their ICU admission or not and therefore this would not have affected the uptake of analgesic drugs between the three groups.

The null hypothesis is rejected, as patients in the aromatherapy massage group required significantly less analgesia ($p<0.05$) on day one and three of their stay in ICU, than those patients who received no intervention.

4.3.3 Section Three: Hypothesis Three

Hypothesis: Patients in intensive care receiving massage only or aromatherapy massage will require less anaesthetic drugs than those not receiving massage only or aromatherapy massage

A panel of experienced colleagues assisted with the analysis of this data and levels of anaesthetic drugs administered on a daily basis were categorised into levels of none or minimal, moderate amounts or high amounts of anaesthetic drugs. Few patients were assigned to the high amounts category and therefore this category was merged into the moderate category and gave two categories (none or minimal and moderate to high). These data was then used in the analysis and logistical regression was applied. Days one to four were selected as the days to analyse the quantity of drugs received by patients for the first intervention. This was so that the quantity of anaesthetic drugs given prior to the intervention and the quantity of anaesthetic drugs received following the intervention could be taken into consideration, up until the second intervention ie day five. These data were then used in the analysis and chi-squared and logistical regression were applied. There were no significant differences between the three groups regarding the quantity of anaesthetic drugs utilised.

Two drugs with anaesthetic properties, propofol and midazolam were administered to patients in differing combinations and doses during their stay in ICU. The analysis strategy employed examined the effects of no intervention, massage only and aromatherapy massage on the levels of anaesthetics received by patients during their stay in ICU.

The level of patients' consciousness was also measured using the newly developed sedation chart (appendix 5) and these scores were analysed to determine any differences between the three groups of patients with regard to their levels of consciousness.

4.3.3.1 Data Set A

4.3.3.1.1 Quantity of anaesthetic drugs received

The majority of patients received anaesthetic drugs in, the none to minimal level, over the first four days of their stay in ICU. On day one patients received more anaesthetic drugs rated as none to minimal (n=85, 81%), whilst only 19% (n=20) received anaesthetic drugs rated as moderate to high. The percentage of patients in the control group who received anaesthetic agents in the moderate to high level was almost half (12%) that of patients who received massage only or aromatherapy massage (22%). Patients' utilisation of anaesthesia was similar over days two, three and four in all three groups. The percentage of patients requiring none to minimal anaesthetic agents increased over the four days. This was expected as patients would be waking up in order to wean from ventilation as their condition improved. Any patients who became more critically ill would demonstrate an increase in anaesthetic drugs in order to maintain stability.

There were no significant differences between the groups regarding the quantity of anaesthetic agents used over days one to four, and there were no significant differences between day one and the other three days with regard to changes in the utilisation of anaesthetic drugs between the three groups.

Table 4.22 Numbers of patients and level of anaesthesia received on days one to four

Day	Level of anaesthesia	Control (n = 32)	Massage only (n = 41)	Aromatherapy massage (n = 32)	Total (n = 105)
1	None to minimal	28 (88%)	32 (78%)	25 (78%)	85 (81%)
	Moderate to high	4 (12%)	9 (22%)	7 (22%)	20 (19%)
2	None to minimal	21 (66%)	26 (63%)	19 (59%)	66 (63%)
	Moderate to high	11 (34%)	15 (37%)	13 (41%)	39 37%)
3	None to minimal	21 (66%)	32 (78%)	22 (69)	75 (71%)
	Moderate to high	11 (34%)	9 (22%)	10 (31%)	30 (29%)
4	None to minimal	25 (78%)	32 (78%)	24 (75%)	81 (77%)
	Moderate to high	7 (22%)	9 (22%)	8 (25%)	24 (23%)

4.3.3.1.2 Sedation Scores.

The sedation scores of patients were recorded during the intervention at four time points, immediately pre-intervention, immediately post intervention, one hour post intervention and four hours post intervention. There were no significant differences between the three groups with regards to their sedation scores at time point one, time point two and time point four. However at time point three (one hour following the intervention) there was a significant difference between the three groups ($\chi^2 = 23.66$, df = 12, p = 0.02). Further investigation of this result found that the sedation scores for patients in the aromatherapy massage group were significantly different from the sedation scores for those patients in the control group; p=0.04 (Mann-Whitney U) and from those patients in the massage only group; p=0.03 (Mann-Whitney U). There were fewer patients in the aromatherapy massage group in category one (awake level) on the sedation score than in the control group or the massage only group. This could mean that patients were more relaxed and asleep and were therefore categorised as something else, or it could mean that patients were more sedated and the intervention had unsettled them. Table 4.22 shows that patients in the aromatherapy massage group did not receive more anaesthetic at time point three, which suggests that something other than the drugs have resulted in patients being less awake. A tentative suggestion is that use of aromatherapy oil in a massage may have resulted in increased sleep for patients, although this finding will require further investigation to substantiate this.

4.3.3.2 Data Set B

Due to the small sample size of data set B, no further analysis was undertaken as false levels of significance may result in type 11 errors. (Whitney 1999).

4.3.3.3 Summary of Section Three

Patients' utilisation of anaesthesia was similar over days two, three and four in all three groups. The percentage of patients requiring none to minimal anaesthetic agents increased over the four days. This was expected as patients would be waking up in order to wean from ventilation as their condition improved. There were no significant differences between the groups regarding the quantity of anaesthetic agents used over days one to four, and there were no significant differences between day one and the other three days with regard to changes in the utilisation of anaesthetic drugs between the three groups.

There were no significant differences between the three groups with regards to their sedation scores at time point one, time point two and time point four. However at time point three (one hour following the intervention) there was a significant difference between the three groups; $\chi^2 = 23.66$, df = 12, p = 0.02. Fewer patients in the aromatherapy massage group were classified as awake compared to patients in both the massage only and the control group. Tentative suggestions have been made that this could be the use of essential oil which has enhanced patients sleep time. This could be a very interesting and useful finding as patients in ICU suffer from ICU psychosis due to the length of time and quantity of anaesthetic drugs received. If the use of essential oils can be shown to have an effect on patients sleep in ICU it would become a very useful adjunct to the nursing and medical care of patients, and could be cost effective as the expenditure on drugs within ICU is immense.

The null hypothesis is accepted, as there were no differences in the quantities of anaesthetic drugs utilised by the three groups.

4.3.4 Section Four: Hypothesis Four

Hypothesis: Patients in intensive care receiving massage only or aromatherapy massage will have reduced anxiety and depression scores, and will demonstrate an improved quality of life on discharge and at one month following discharge from intensive care than those not receiving massage only or aromatherapy massage

The whole data set was used in this analysis. There was no significant difference in the length of stay in ICU between the three groups. The control group had a mean length of stay of 12 days (SD=12.03), the massage group had a mean length of stay of 10 days (SD=10.16), whilst the aromatherapy group had a mean length of stay of 11 days (SD=10.01).

All patients within this analysis had received at least one massage or aromatherapy massage if in the experimental groups. Various methods of weighting the data to account for the total number of massages received were examined but none were considered to be appropriate for use with the data (appendix 9).

The first questionnaires were completed on the ICU immediately before discharge to the ward. The second questionnaires, which were completed one month after discharge from ICU, were either completed on the ward within hospital where the patient remained, or they were posted, to be completed at home and returned to the hospital in the stamp addressed envelope. The data were analysed in three sections.

- the group of patients who completed the first questionnaires (HAD and SF36) on discharge from ICU.

- the group of patients who completed the second questionnaires (HAD and SF36) one month after discharge from ICU.
- the group of patients who were able to complete both the first questionnaire on discharge from ICU and the second questionnaire one month after discharge from ICU.

Data were analysed in this way to account for any differences between the same patients who has completed both questionnaires, and to achieve a larger sample, patients who completed either the first or second questionnaire were also examined.

4.3.4.1 Analysis of the patient group who completed the first set of questionnaires at discharge from ICU.

A proportion of patients did not complete the first set of questionnaires at discharge from ICU (n=87, 58%). This was due to, patients dying on ICU (n=52, 60%), patients being too ill at discharge from ICU to complete questionnaire (n=5, 6%), patients not completing through choice or another unknown reason (n=30, 34%)

Of the 150 patients recruited to the study a total of 49 (33%) patients had received at least one massage during their stay on ICU and completed the first set of questionnaires at discharge from ICU. Eighteen patients (37%) responded from the control group and the aromatherapy massage group and 13 (26%) patients responded from the massage only group.

4.3.4.1.1 Hospital Anxiety and Depression Scores

4.3.4.1.1.1 Anxiety

Patients in the control group had a mean anxiety score of 9 (SD=4.55), those patients in the massage only group had the highest mean anxiety score of 10.69 (SD=5.17), whilst those patients in the aromatherapy massage group demonstrated the lowest mean anxiety score of 8.67 (SD=5.37) There were no significant differences between patients in the three groups regarding the mean anxiety scores as measured with the HAD scale, at discharge from ICU. All scores were below the clinical level for anxiety. Patients in the massage only group demonstrated the highest scores, which were close to the level for clinical anxiety.

Table 4.23 Mean (standard deviation) anxiety scores at discharge

	control n = 18	massage only n = 13	aromatherapy massage n = 18
Anxiety score at discharge from ICU	9 (4.55)	10.69 (5.17)	8.67 (5.37)

4.3.4.1.1.2 Depression

Patients in the control group had a mean depression score of 8 (SD=4.45), those in the massage only group demonstrated the highest mean depression score of 8.85 (SD=4.93) whilst patients in the aromatherapy massage group showed the lowest mean depression score of 7.56 (SD=5.45). All scores were below the clinical level for depression. There were no significant differences between the three groups with regards to the mean depression score at discharge from ICU measured using the HAD scale.

Table 4.24 Mean (standard deviation) depression scores at discharge

	control n = 18	massage only n = 13	aromatherapy massage n = 18
Depression score at discharge from ICU	8 (4.45)	8.85 (4.93)	7.56 (5.45)

4.3.4.1.2 Health Status

In relation to the mean SF-36 scores patients in the control group demonstrated lower mean scores for health status in four of the eight domains (role limitation; physical, social function, energy and pain) than patients in the massage only or aromatherapy massage groups.

Patients in the control group demonstrated similar mean scores for the mental health domain (51.78, SD 21.05) to those patients in the massage only group (51, SD 18.85), and these scores remained lower than patients' mental health scores in the aromatherapy massage group (59.56, SD 24.27).

The mean score for the domain of role limitation (mental) was much lower for patients in the massage only group (23.07, SD 36.98), than for patients in the control group (53.7, SD 48.7) and aromatherapy massage group (45.09, SD 49.92).

There were no significant differences between or within the three groups of patients for each of the eight domains using multivariate analysis of variance. Table 4.25.

Table 4.25 Summary of mean and standard deviation for the eight domains of the SF36 questionnaire at discharge from ICU

	control (n = 18)		massage (n = 13)		aromatherapy massage (n = 18)		
SF36	mean	std. dev.	mean	std. dev.	mean	std. dev.	Sig.
Physical Function	39.72	32.88	41.15	35.07	33.61	34.21	ns
Role limitation; physical	13.89	33.46	16.67	38.93	16.18	34.17	ns
Role limitation; mental	53.7	48.7	23.07	36.98	45.09	49.92	ns
Social function	31.46	36.79	45.33	27.78	41.95	40.6	ns
Mental health	51.78	21.05	51	18.85	59.56	24.27	ns
Energy	29.17	24.27	34.58	22.91	38.89	26.6	ns
Pain	40.72	38.67	42.57	32.77	51.2	38.12	ns
Health perceptions	53.22	27.97	45.42	22.06	56.89	23.95	ns

There were no significant findings relating to anxiety, depression or health status in all three groups of patients who completed the questionnaires at discharge from ICU.

4.3.4.2 Analysis of the patient group who completed the second set of questionnaires one month after discharge from ICU.

A proportion of patients did not complete the second set of questionnaires one month after discharge from ICU (n=99, 65%). This was due to, patients dying on ICU (n=65, 66%), patients remaining too ill one month after discharge from ICU to complete questionnaire (n=4, 4%), patients not completing through choice, or another unknown reason (n=30, 30%).

Of the 150 patients recruited to the study a total of 45 (30%) patients received at least one massage during their stay on ICU and completed the second set of questionnaires one month after discharge from ICU. Thirteen patients (29%) responded from the control group, 15 (33%) patients responded from the massage only group and 17 (38%) patients responded from the aromatherapy massage group.

At the time of completion of the second questionnaires 15 (33%) of patients remained in hospital and 30 (67%) had been discharged home.

4.3.4.2.1 Hospital Anxiety and Depression Scores

4.3.4.2.1.1 Anxiety

Patients in the control group had a mean anxiety score of 6.54 (SD=2.9), those patients in the massage only group had the highest mean anxiety score of 8.87 (SD=3.76), whilst those patients in the aromatherapy massage group demonstrated a mean anxiety score of 6.71 (SD=5.25) There were no significant differences between patients in the three groups regarding the mean anxiety scores as measured with the H.A.D. scale, one month after discharge from ICU. All mean scores were below the clinical level for anxiety.

Table 4.26 Mean (standard deviation) anxiety scores at one month post discharge from ICU

	control n = 13	massage only n = 15	aromatherapy massage n = 17
Anxiety score at one month post discharge from ICU	6.54 (2.9)	8.87 (3.76)	6.71 (5.25)

4.3.4.2.1.2 Depression

Patients in the control group demonstrated the highest mean depression score of 7.62 (SD=3.5), those in the massage only group had a mean depression score of 6.33

(SD=4.08) and patients in the aromatherapy massage group showed a similar mean depression score of 6.29 (SD=4.73) to those patients in the massage only group.

There were no significant differences between the three groups with regards to the mean depression score one month after discharge from ICU measured using the H.A.D. scale. All mean scores were below the clinical level for depression.

Table 4.27 Mean (standard deviation) depression scores at one month post discharge from ICU

	control n = 13	massage only n = 15	aromatherapy massage n = 17
Depression score at one month post discharge from ICU	7.62 (3.5)	6.33 (4.08)	6.29 (4.73)

4.3.4.2.2 Health Status

One month after discharge from ICU, the group of patients receiving massage only, demonstrated the poorest health status, with lowest mean scores in five of the eight domains (role limitation; physical, role limitation; mental, social function, mental health and pain).

Scores relating to mental health and pain were good, whilst scores relating to social function and role limitation had deteriorated. This may be because patients continue to be unable to be independent and socialise even after they have returned home. Patients often feel frightened and vulnerable following a critical illness and this may be one reason they feel unable to socialise.

Table 4.28 Summary of mean and standard deviation for the eight domains of the SF36 questionnaire one month following discharge from ICU

	control (n = 13)		massage (n = 15)		aromatherapy massage (n = 16)		
SF36	mean	std. dev.	mean	std. dev.	mean	std. dev.	Sig.
Physical Function	30	36.17	32.50	35.01	36.47	32.20	ns
Role limitation; physical	22.92	41.91	1.79	6.68	6.25	25	ns
Role limitation; Mental	36.36	50.45	2.56	9.24	26.66	40.24	ns
Social function	35.02	33.88	27.38	20.06	36.08	28.52	ns
Mental health	68	21.60	54.4	16.41	67.5	22.34	ns
Energy	33.46	24.53	32.67	16.02	31.25	21.41	ns
Pain	55.52	33.94	46.62	19.77	61.08	34.9	ns
Health perceptions	49.45	27.92	55.53	26.76	49.06	24.85	ns

In relation to the SF36 scores at discharge from ICU there were no significant differences for the eight domains between or within the three groups using analysis of variance.There were no significant findings relating to anxiety, depression and quality of life between the three groups, one month after discharge from ICU.

4.3.4.3 Analysis of the group who completed the first set of questionnaires at discharge from ICU and the second set of questionnaires one month after discharge from ICU.

The final part of the analysis is based upon those patients who were able to complete two questionnaires, i.e. at discharge from ICU and one month later. After one month from completion of the first questionnaire, 6 (19%) patients remained in hospital and 25 (81%) patients had been discharged home. All patients had received at least one intervention.

A total of 31 patients responded to both the first questionnaire at discharge from ICU, and the second questionnaire one month after discharge from ICU and had received at least one intervention; 9 (28%) patients from the control group, 11 (36%) patients from the massage only group and 11 (36%) patients from the aromatherapy massage group.

4.3.4.3.1 Hospital Anxiety and Depression Scores

4.3.4.3.1.1 Anxiety

At discharge from ICU patients in the massage only group had the highest mean anxiety score of 10.55 (SD=5.28), and one month later 9.27 (SD=3.5). Patients in the aromatherapy massage group demonstrated similar scores of 10 (SD=5.71) at discharge, but demonstrated a greater reduction in anxiety score one month later 8.45 (SD=5.63). The control group had the lowest mean anxiety score of 8.44 (SD=4.19) at discharge and one month later this had reduced to 6.89 (2.62). There were no significant differences between the three groups regarding the anxiety scores as measured with the H.A.D. scale, at discharge from ICU or one month later. Table 4.29.

Table 4.29 Mean (standard deviation) anxiety scores at discharge and one month post discharge from ICU

	control n = 9	massage only n = 11	aromatherapy massage n = 11
Anxiety score at discharge from ICU	8.44 (SD = 4.19)	10.55 (SD = 5.28)	10 (SD = 5.71)
Anxiety score after one month post discharge from ICU	6.89 (SD = 2.62)	9.27 (SD = 3.5)	8.45 (SD = 5.63)

Repeated measures analysis of variance demonstrated no significant differences for anxiety between or within the three groups over the time between discharge from ICU and one month after discharge from ICU.

4.3.4.3.1.2 Depression

Patients in the control group demonstrated the lowest mean depression score of 7.89 (SD=4.34) at discharge from ICU but this had increased to 8 (SD=3.61) one month later. Patients in the massage only group demonstrated a mean depression score of 8.09 (SD=4.99) at discharge and one month later this had reduced to 7.55 (SD=4.03). Patients in the aromatherapy massage group showed the highest mean depression score of 9.18 (SD=5.62) at discharge from ICU which showed the greatest reduction to 8 (SD=5.08) one month later. There were no significant differences in the level of depression between the three groups at discharge from ICU or at one month later. Table 4.30.

Table 4.30 Mean (standard deviation) depression scores at discharge and one month post discharge from ICU

	control n = 9	massage only n = 11	aromatherapy massage n = 11
Depression score at discharge from ICU	7.89 (SD = 4.34)	8.09 (SD = 4.99)	9.18 (SD = 5.62)
Depression score after one month post discharge from ICU	8 (SD = 3.61)	7.55 (SD = 4.03)	8 (SD = 5.08)

Repeated measures analysis of variance demonstrated no significant differences for depression between or within the three groups over the time between discharge from ICU and one month after discharge from ICU.

4.3.4.3.2 Health Status

Multivariate analysis of variance undertaken to determine any differences between and within patient groups over time found that there were significant differences between the domains of role limitation mental using the SF36. Table 4.31.

Table 4.31 Summary of mean and standard deviation for the eight domains of the SF36 questionnaire at discharge and one month post discharge from ICU

	control		massage		aromatherapy massage			
	mean std. dev.	mean std. dev.	mean std. dev.	mean std. dev.	mean std. dev.	mean std. dev.	Significance [1]	
SF36	Time One	Time Two	Time One	Time two	Time One	Time Two	Time One	Time Two
Physical Function	48.2 33.59	32.86 36.36	45.36 37.18	37.81 35.73	37.62 35.52	35.75 32.58	ns	ns
Role limitation; physical	13.54 30.38	21.15 40.63	23.08 43.85	1.56 6.25	15.48 32.09	5.26 22.94	ns	ns
Role limitation; mental	47.22 47.1	36.11 48.11	28.56 41.05	2.22 8.6	49.2 49.01	23.52 38.67	ns	* $F(2,41) = 3.28$ $p = 0.048$ $^{**}\chi^2 = 5.45$, df 2, $p = 0.066$
Social function	31.92 34.86	33.31 33.17	49.53 30.62	28.08 18.87	47.45 39.41	34.53 27.43	ns	ns
Mental health	51.67 21.29	65.14 23.35	54.46 21.94	52.94 16.28	63.64 23.84	66.94 20.61	ns	$^{**}F(2,47) = 2.47$ $p = 0.096$ $^{**}\chi^2 = 4.87$, df 2, $p = 0.088$
Energy	28.96 22.26	31.07 25.21	32.69 22.97	32.94 15.01	40.0 24.49	29.74 20.58	ns	ns
Pain	39.79 35.57	53.94 33.15	46.99 35.18	50.28 21.18	51.98 37.29	61.08 35.39	ns	ns
Health perceptions	51.79 25.88	50.92 27.1	48.23 23.43	56.88 25.56	58.48 23.13	47.22 23.96	ns	ns

* significant at 5% level
1 F test and Kruskal-Wallis test applied
** significant at 10% level

Parametric tests were conducted of analysis of variance. In addition the non-parametric equivalent was also applied as the standard deviations were large and related to size of mean.

4.3.4.4 Summary Section Four

Patient scores for anxiety in all three groups declined between the two sets questionnaires at discharge from ICU and one month later. Patient scores for depression declined in both the massage only and the aromatherapy massage groups between discharge and one month later, but there was no change in scores for patients in the control group. There were no significant differences between the groups in anxiety and depression scores and there were no differences between the groups over time.

In relation to SF36 scores, patients did not demonstrate any differences between the groups, except for in the domain of role limitation (mental). This score however must be viewed with caution due to the number of tests undertaken to reach significance. Also the scores for patients within the massage group appear to be very different to the other scores

In summary there were no significant results for any of the psychological variable measured and therefore the null hypothesis is accepted.

4.4 Summary

In summary, significant results were found in three of the variables measured, diastolic blood pressure, quantity of analgesic drugs received and changes in the levels of consciousness (measured by the sedation score, appendix 5). Table 4.32

A significant difference in diastolic blood pressure between the three groups four hours after the second massage was demonstrated using ANOVA,

$F(2,28)=3.37; p=0.049$. Further investigation using t-tests demonstrated that the variation lay between patients who received aromatherapy massage and patients in the control group. Patients who had received aromatherapy massage had a lower diastolic blood pressure by 14mmHg.

A significant difference between the three groups in the quantity of analgesia used on the day before the first intervention (day one) compared to the day following the first intervention (day three) was demonstrated using chi-square, $p<0.05$. This was investigated further using logistical regression. The significance occurred between patients in the control group and patients who received aromatherapy massage, $p<0.05$. On day one both patients in the control group and patients in the aromatherapy massage group were receiving similar amounts of analgesia. On day three there were more patients in the control group who were receiving analgesia in the moderate to high category compared to patients in the aromatherapy massage group.

The third finding was a significant difference in sedation scores between the three groups demonstrated using chi-square, $\chi^2=23.66$, df=12, $p=0.02$. This was investigated further and the significance was found between patients who had received aromatherapy massage compared to patients in the control group, $p=0.04$ (Mann-Whitney U), and patients who received massage only, $p=0.03$ (Mann-Whitney U) One hour following the first intervention there were more patients in the asleep category who had received an aromatherapy massage compared to those patients in the control and massage only groups.

All three statistical results for the group of patients who received aromatherapy massage compared to the group of patients who received no intervention (control). It is interesting that there are no significant results for patients who received massage only. A tentative suggestion that aromatherapy has more effect than massage only is made. Aromatherapy has been shown to have some effects compared to patients who received no intervention (control). There were no significant results for patients who received massage only.

Table 4.32 Summary table of significant results

Variable	Time point	Statistical test	Significance	Findings
Diastolic blood pressure	Day 5 4 hours after 2nd intervention	ANOVA	$P<0.05$	Patients who received aromatherapy massage had significantly lower diastolic blood pressure compared to patients in the control group
Analgesia	Day 3 Day following the 1st intervention	Logistical Regression	$P<0.05$	Patients in aromatherapy massage group used significantly less analgesia than those patients who received no intervention
Sedation score	Day 2 One hour following the 1st intervention	Chi-squared	$P<0.05$	Patients in the aromatherapy group were asleep more often compared to those patients in the control and massage only groups
SF36, Role limitation (mental)	One month post discharge from ICU	F test Kruskall Wallis	$P<0.05$ $P<0.07$	These results need to be viewed cautiously due to the number of statistical tests undertaken to achieve significance

5 DISCUSSION

The study evaluated the effects of massage only and aromatherapy massage versus a control group, on both physical and psychological variables of patients who were critically ill in an intensive care unit. A randomised controlled trial approach was utilised. Discussion of the findings has been presented in following six sections;

5.1. Physiological effects of the intervention

5.2. Psychological effects of the intervention

5.3. The use of randomised controlled trial methodology

5.4. Future work

5.5. Limitations

5.6. Summary

5.1 Physiological Effects of the Intervention

5.1.1 Cardiovascular parameters

The physiological variables of heart rate, systolic blood pressure, diastolic blood pressure and respiratory rate were all used as dependent variables to evaluate the effect of massage only and aromatherapy massage. The effect on heart rate was examined first. Minute changes in heart rate occurred over time in all three groups of patients. These changes were not significant and no patterns of change emerged. Reasons why this may have occurred are patients who are critically ill demonstrate spontaneous changes in cardiovascular parameters due to the unstable nature of their illness and therefore the time points used to measure any effect may not have been the most informative. If the interventions were carried out when patients were more stable and less prone to spontaneous changes in cardiovascular parameters, this may make any effect more evident.

The majority of earlier studies where heart rate has been used as an indicator of effect have shown no change following massage only, but studies using aromatherapy massage have demonstrated significant reductions in heart rate in five studies (Fakouri and Jones 1987, Field et al 1992, Meek 1993, Field et al 1998, Hayes and Cox 2000). Three similar studies undertaken on critically ill patients mirrored the findings of this study and found no changes in heart rate relating to aromatherapy massage (Buckle 1993, Stevenson 1994, Dunn et al 1995). All of these studies used randomised controlled trial methodology and two of the studies (Stevenson 1994, Dunn et al 1995) used large sample sizes (n = 100 and n = 122 respectively) increasing the confidence that can be placed on the findings.

Secondly the effects of massage only and aromatherapy massage on systolic blood pressure were examined. Small changes in mean systolic blood pressure occurred over time for all patients in the study. The group of patients who received massage only, demonstrated a reduction in mean systolic blood pressure immediately following the massage after both the first and the second massage. Although these results were not significant they did identify a pattern of change. Previous studies (n=10) examining the effects of massage only on blood pressure found reductions in systolic blood pressure in all studies. Only three of these studies were randomised controlled trials (White-Traut and Goldman 1988, Fraser and Ross Kerr 1993, Corley et al 1995). Three of the studies demonstrated significant differences in systolic blood pressure between patients who received a massage and those who did not (Fakouri and Jones 1987, $p<0.01$; Meek 1993, $p<0.001$; Hayes and Cox 2000, $p<0.001$). All three studies used a quasi-experimental approach and had small sample sizes. Fakouri and Jones (1987) examined 18 elderly patients, Meek (1993) examined

30 adults in an hospice and Hayes and Cox (2000) examined 25 critically ill adults. Only one study (Basnyet 1999) that used aromatherapy massage suggested that large changes in systolic blood pressure occurred. This was a randomised controlled pilot study, but the extent of the difference between the groups was not tested statistically. A diminutive reduction in systolic blood pressure was observed in all studies. No groups of patients within this current trial demonstrated any significant differences in systolic blood pressure.

Thirdly, the effects of massage and aromatherapy massage on diastolic blood pressure were examined. Small changes in the mean diastolic blood pressure occurred in both experimental groups in this study. There was a significant reduction in the mean diastolic blood pressure between patients in the control group and patients in the aromatherapy massage group (p=0.035) after four hours following the second aromatherapy massage. The range in diastolic blood pressure between the two groups was 14mm.Hg. A variation of 14mm.Hg in diastolic blood pressure is of clinical importance and could have a beneficial effect on patient care. There were no significant changes in diastolic blood pressure in previous studies using aromatherapy massage. Only two studies (Stevenson 1994, Dunn et al 1999) measured diastolic blood pressure and neither study found any significant differences between groups, although both these studies only measured the effects of a single aromatherapy massage. Neither of these studies measured the effects of a consecutive massage and the result from this study could be due to an additive effect of aromatherapy massage.

In summary, regarding the physiological effects of massage only and aromatherapy massage (experimental groups) compared to no intervention (control) there were no significant findings relating to changes in heart rate. It was interesting to note that patients who received massage only demonstrated a decrease in the mean systolic and mean diastolic blood pressure immediately following the intervention on two consecutive occasions. Although these changes were not significant they demonstrated a pattern of change that would be interesting to investigate further. These changes were also too small to have any clinical consequence. There was however, a significant finding relating to patients who received aromatherapy massage. These patients demonstrated a lower diastolic blood pressure four hours after the second massage (p=0.035). This could suggest an additive effect of repetitive massages. Some previous studies have produced findings that implied a cumulative influence of massage (Corner et al 1995, Kite et al 1998, Wilkinson et al 1999). This may be due to patients feeling more relaxed as they become familiar with; (i) receiving a massage, and (ii) with the therapist.

The physiological variable of respiratory rate was omitted from the analysis due to the limited effect that the intervention could have imposed on it. Patients in the ICU who were mechanically ventilated were unable to make changes in their respiratory rate due to it being controlled. Other studies have used respiratory rate as a physiological variable and have demonstrated an effect, Ferrell-Torry and Glick (1993) used massage only, and Woolfson and Hewitt (1992), Buckle (1993) and Bell (1993) used aromatherapy massage compared to patients who received no intervention. However, the studies that demonstrated an effect did not use patients that required ventilation and this suggested that these patients were not critically ill.

This has caused some difficulty when comparing results between studies. To interpret future research more accurately it is important that the patient populations used in studies are made explicit so that more informed or legitimate comparisons can be made.

5.1.2 Drug Utilisation

5.1.2.i Analgesia

There were no differences between the three groups in the quantity of drugs received, on day one, before the intervention. However there was a significant difference ($p<0.05$) between day one and day three, when patients in the aromatherapy massage group received less analgesia on day three (the day following the intervention) compared to patients in the control group.

There were no significant effects on patients' level of pain in relation to the interventions. One-month post discharge from ICU all three groups of patients demonstrated an observable increase in their pain scores using the Short Form 36 (Jenkinson et al 1993), although this was not statistically significant. This was probably due to a lack of analgesia and an increased awareness of sensation. Patients receive comprehensive pain management in ICU as demonstrated by the large doses of analgesia used.

Five studies examining the effects of massage only on pain found significant reductions in patients' reports of pain (Ferrell-Torry and Glick 1993, Weinrich and Weinrich 1990, Field et al 1997, Field et al 1998, Hulme et al 1999). Three studies using aromatherapy massage were able to demonstrate a decrease in pain (Woolfson and Hewitt 1992, Cooper 1995, Papadopoulos et al 1999). All the studies undertaken in midwifery demonstrated an effect on pain in women (Reed and Norfolk 1993, Burns and Blamey 1994, Dale and Cornwell 1994, Burns et al 2000). Kaada and Torsteinbo (1989) attempted to explain why massage has an effect on pain relief. They examined the effect of massage on the increase of plasma B-endorphins and demonstrated that the use of a 30 minute massage resulted in a moderate increase of plasma B-endorphins which lasted for about one hour (p=0.025). One theory as to the effect of massage on the decrease in pain is the release of plasma B-endorphins which is linked with pain relief and associated with feelings of well being post massage.

Even though a pain scale was developed for use in this study it may not have been sensitive enough over the given time period to record any changes in pain. Patients were either sedated or were well enough to be discharged to the ward. Pain control in ICU is competently managed (as mentioned previously) and patients should be mainly pain free and therefore the extreme end of the pain scale was utilised (ie minimal score). The marked 'floor effect' shown by the pain ratings for this self-report method reduced the ability of this study to demonstrate a change in pain level across study groups. In addition, critically ill patients involved in this study were probably not an appropriate group to be recording changes in pain. A patient group who were awake and able to communicate pain levels on a more regular basis would probably be a more appropriate group of patients to study in order that substantial evidence of the effects of aromatherapy massage on pain could be obtained. A further factor to explain the low variation of scores across groups may have been associated with the study design, regarding when pain measures were administered. The assessment of pain was made at stipulated regular times which may not have been the most appropriate times to measure the effect of massage on pain. It would have been worthwhile measuring the effect of massage on pain by providing the massage when the patient was in pain. The effect of massage may then be revealed. The design issues however, of implementing such a study would not be straightforward.

In summary, those patients who received massage only or aromatherapy massage required less analgesia than those patients who received no intervention. There were significant differences between patients who received aromatherapy massage and patients who received no intervention on the day following aromatherapy massage. Two reasons for this may be that the aromatherapy massage (i) relaxed patients so they did not did not feel as much pain as the control group and (ii) patients were more able to cope with the pain and required less analgesia. There is little evidence to suggest that either of these reasons is the more likely cause for the reduction in analgesia utilised, however, the dilemma has produced an interesting area on which to focus future research.

5.1.2.ii Anaesthetic

No previous work has been undertaken which examined the effects of massage and aromatherapy massage on the quantity of anaesthetic drugs utilised by patients or the sleep levels of patients in ICU. In addition there is only anecdotal evidence to suggest that bergamot oil has relaxing properties. However, if any relaxing effects, leading to enhanced sleep or a decrease in drug requirement could be shown there would be profound implications for both patient comfort and patient costs. Essential oil of bergamot is cheaper to use than anaesthetic drugs such as propofol and would

therefore be cost-effective by reducing drug usage and reducing patient days spent on ICU. Inpatient days could be reduced due to speedier weaning from the ventilator because of smaller amounts of drugs needing to be excreted from the body. There is a lot of controversy regarding the use of propofol and its safety in large concentrations and any reduction in its use would be beneficial. Essential oils may be an alternative source of relaxation to assist in the reduction of anaesthetic drug concentrations.
The amount of propofol used within each of the groups over time did not vary greatly. Patients' utilisation of propofol was similar in all three groups over days two to four of the study. The percentage of patients requiring anaesthesia decreased over the first four days of the study. This was expected as patients would be waking up in order to wean from the ventilator as their condition improved. There were no significant differences between the groups regarding the quantity of anaesthetic drugs utilised over days one to four of the study.

No studies have examined the effects of massage or aromatherapy massage on sleep patterns and the use of anaesthetic agents in ICU. Some studies have examined the effects of aromatherapy oils on sleep patterns using inhalation methods or vaporisers (Hardy 1991, Williams 1991). Hardy (1991) found that in elderly mentally ill patients night-time sleeping improved and Williams (1991) found that a single patient felt more relaxed and was able to sleep. However these studies did not use aromatherapy massage.

Sedation scores measured around the interventions demonstrated significant differences between patients in the aromatherapy massage group and patients in the control group (p=0.04), and patients in the aromatherapy massage group and patients in the massage only group (p=0.03) one hour after receiving the first aromatherapy massage. There were significantly less patients in the aromatherapy massage group who were in the 'awake' category. This could suggest that patients in the aromatherapy massage group were more relaxed and able to sleep. Also, these patients required less anaesthetic drugs compared to patients in the control group, which again indicated that the use of bergamot oil might affect relaxation.

These findings suggest that the use of bergamot oil in a massage has a sedative or relaxing effect on patients in intensive care compared to massage only or no intervention. This is the first study to demonstrate this effect. It is an important finding that warrants replication in a future study.

5.2 Psychological Effects of the Intervention

The effects of massage only and aromatherapy massage have more recently been investigated using psychological measures and have provided some evidence of a reduction in anxiety (Field et al 1998, Basnyet 1999, Wilkinson et al 1999, Burns et al 2000) and enhanced mood (Buckle 1993, Dunn et al 1995).

When considering the wealth of anecdotal evidence which suggests that essential oils are an excellent way of improving psychological well being, it is remarkable that so little empirical work has been undertaken to substantiate these claims. Also, specifically relating to the effects of bergamot oil there is only anecdotal evidence relating to the effects on depression. This study has attempted to address this problem by examining depression as an outcome variable.

5.2.1 Anxiety and depression

Results showed that all patients were below the clinical level for anxiety and depression when they were discharged from ICU regardless of their experimental grouping. Those patients who received aromatherapy massage had the lowest scores for both anxiety and depression, whilst those patients who received massage only had the highest scores when discharged from ICU. Results also showed that one month following discharge from ICU all patients were below the clinical level for anxiety and depression, regardless of their experimental grouping. Patients who received aromatherapy massage again demonstrated the lowest depression scores. There were no significant findings. Patients who responded to both sets of questionnaires at discharge and one month later did not demonstrate any significant differences between depression and anxiety at discharge compared to one month later (ie over time).

These findings are in contrast with the increasing literature that has demonstrated significant differences in anxiety scores between groups of patients receiving massage only or aromatherapy massage. Three studies using massage only were able to demonstrate a significant reduction ($p<0.05$) in anxiety (pg 73). There were ten studies of aromatherapy massage that demonstrated a reduction in anxiety (pg 109). Most of these studies reached statistical significance. It was also shown that aromatherapy massage had a greater effect than massage alone and that more massages enhanced the effects.

This study may not have shown any effects in relation to anxiety due to the type of patients studied. Patients in other studies have usually not been critically ill and were probably more alert and aware of their hospitalisation. Patients who have undergone cardiac surgery have demonstrated reduced anxiety scores (Woolfson and Hewitt 1992, Stevenson 1994) but these patients may have had higher initial anxiety scores due to the knowledge of their pending critical heart surgery and overnight stay in ICU. Patients in general intensive care units are often admitted without prior knowledge, and their stay is often longer than pre-booked cardiac surgery patients. Due to no previous knowledge of their admission (patients are usually admitted as an emergency) and a more lengthy time spent in ICU (which results in these patients being more likely to be sedated with anxiolytic drugs) these patients may not feel as anxious as patients in cardiac intensive care units. This study demonstrated no significant differences in anxiety scores between the groups and over time.

5.2.2 Quality of Life

There were no significant findings relating to quality of life between the groups. Two studies (Corner et al 1995, Walsh and Wilson 1999), which examined quality of life, were also unable to demonstrate any differences between groups of patients.

Further work needs to be undertaken to establish the extent of patients' problems relating to anxiety and depression and to compare these in relation to the use of antidepressant drugs and aromatherapy following an admission to ICU. Future research should investigate the merits of generic versus specific health status measures for patients in ICU and establish their usefulness in evaluating outcomes of health care and services. It is important to use effective health measurement scales for patients in ICU such as the Hospital Anxiety and Depression Scale (Zigmond and Snaith 1983) which is a valid and reliable measure and is short and simple to complete, but it is also important to test the usefulness of other measures such as the Profile of Mood States (McNair et al 1981) and the State-Trait Anxiety Inventory (Spielberger et al 1983). The effectiveness of other measures need to be determined before the expensive and lengthy process of developing new measures is undertaken.

It would be interesting to examine the effects of massage only and aromatherapy massage on the relatives of patients in ICU. The care of relatives is a large part of the nurse's role in ICU as relatives are often distraught and unable to accept that their loved one is critically ill. It would be useful to examine the impact of the therapies on relative's levels of anxiety and depression and their quality of life and coping mechanisms. Previous studies (Jamerson 1996, Rukholm et al 1991) have found that relatives find admission of a loved one to ICU anxiety provoking and the use of aromatherapy massage may be one way of helping relatives to cope with their stress and anxiety.

5.3 Use of Randomised Controlled Trial Methodology

Randomised controlled trial methodology was selected for this study. There are many arguments that have been put forward to discriminate against the use of this methodology particularly in relation to complementary therapies (pgs 33-43). However this methodology proved to be useful when addressing the research question within this study.

The use of randomised methodology allowed patients who complied with the inclusion/exclusion criteria and consented to be part of the study to be randomly allocated to one of three groups for participation within the study. This was a crucial element as it ensured that all participants had an equal chance of being allocated to any of the groups and it provided equivalent groups for comparison. The use of controlled methodology also enabled the comparison of a control group with two experimental groups (massage only and aromatherapy massage) in order to assess the effectiveness of the intervention.

This methodology was successfully used in the study because the work was undertaken in an intensive care unit which is a controlled environment enabling the physiological parameters to be measured objectively. The degree of controlling experimental conditions has resulted in arguments from complementary therapists. They argue that no conclusions are ever drawn from randomised controlled trials in complementary therapies because the wrong objective measures are used and that subjective measures should be utilised along with other less controlling methodologies such as single case studies. One particular argument that has been forwarded is that randomised controlled trial methodology in complementary therapy research does not do justice to the individualised, person-centred approach of many complementary therapies and they do not consider patient preferences. One example surrounded the use of a set protocol for the massage procedure and the use of singular aromatherapy oils. Complementary therapists suggest that for the treatment to benefit the patient it needs to be tailored to each person individually and often results in massage which does not follow a set protocol and uses a mixture of up to three oils. If however everyone was being treated for the same condition, for example stress or anxiety then the treatment should all be identical in order to demonstrate any effect between individuals.

An increasing number of studies into complementary therapies need to withstand rigorous scientific scrutiny and this may suggest that randomised controlled trials have value in addressing this. In order to undertake good quality research, studies need to be carefully designed to avoid wasted effort and finances. More preparatory work needs to be undertaken when planning future studies and more effort is required in preparing the correct research questions, which will then inform the appropriate research methodology.

The current number of studies that have used massage or aromatherapy massage and randomised controlled trial methodology is 24 (45%) and a further 16 (30%) used a quasi-experimental approach. This showed that 75% (n=40) of studies have used experimental methodology to produce evidence of the effects of massage and aromatherapy and that the majority of published research uses this approach. However, even though these figures look promising the quality of the studies is under scrutiny, with many of these using very small sample sizes (Sims 1986, n=6; Hardy 1991, n=4, Hudson 1996, n=9; Lindsay et al 1997, n=8; Brownfield 1998, n=9; Walsh and Wilson 1999, n=4).

Future arguments should not circulate around the methodology but around the research question. If a randomised controlled trial is the best methodology to answer the question then this should be utilised. Richardson (2000) suggested that the best methodology for investigating complementary therapies is the one that is the most scientifically appropriate to answer the research question in the context in which it exists. Ernst (1997) also recommended that the research methodology must be appropriate to the research question.

There has been limited work previously undertaken in the area of complementary therapies, which has not been rigorous or systematic in nature (Williams 1991, Woolfson and Hewitt 1992). MacMahon and Kermode (1998) suggested one reason for this may be due to the vast majority of carers in clinical settings where research is undertaken (such as elderly and psychiatric care homes) having no formal qualifications or training and are not part of a culture which encourages or rewards research practice. They also suggested that data may exist, but it has been suppressed by a culture that does not value it. Price and Price (1995) put forward a poor argument that it would be too costly to evaluate the efficacy of aromatherapy because of the number of oils that would need examining.

If some benefits can be demonstrated using randomised controlled trials (by providing vital ground work) then this would provide a step towards using other methodologies, such as case studies, and help to gain further funding in a relatively under funded and under researched area. Sceptics are more likely to be persuaded of any benefits to the use of complementary therapies if good quality randomised controlled trials are used, which they readily understand and believe to be the gold standard of research methodology.

The implications of this study suggest that a randomised controlled trial is a suitable methodology to use for examining complementary therapies that can add to the limited body of knowledge and may have more influence with traditional scientists. It was selected as the most suitable research methodology to address the research question. Future research may need to take a more controlled approach in order to demonstrate effects but that they can be interlaced with less conventional methodologies such as case studies. A further advantage of using randomised controlled trial methodology to investigate relatively new areas of work is the ability to estimate an effect size of the intervention and combine the results of a number of RCTs using meta-analysis.

The use of a gold standard methodology to evaluate these therapies is required to produce evidence that will be utilised by all professions within healthcare. The recent randomised controlled trials (Kerr 1993, Corner et al 1995, Richards 1998, Wilkinson et al 1999) have also utilised some qualitative methodology in an attempt to address some of the more holistic issues that randomised controlled trials do not address. Triangulation is probably a useful way of examining complementary therapies as it incorporates different outcomes that may be difficult to measure in other research designs. It would be useful to develop reliable and valid measures to measure subjective variables, such as the effects of therapeutic relationships. Biley and Freshwater (1999) pointed out that nursing research has shifted away from the use of quantitative methodology and is utilising qualitative methods which emphasize a greater degree of individuality, humanism, participation and interaction. It is important to ensure that the research question is sufficient in order to address the pertinent issues, so that the correct research methodology is selected.

Experimental methodology and the clinical trial have a legitimate and important role to play but exclusive reliance on these strategies can have a constricting influence on the research enterprise in complementary therapies. Brewin and Bradley (1989) suggested that randomisation could be extended to include an extra patient group, which chooses their treatment (compared to the control group and the experimental group) and the effects measured to determine the effect taking into consideration the patient preference. Other research methodologies need to be developed to build upon existing evidence and to extend the framework for future research into complementary therapies. Triangulation would be a useful methodology to use because elements of both rigid objective measures can be integrated with subjective measures that may highlight some beneficial elements of complementary therapies, which are difficult to demonstrate using conventional randomised controlled trials.

5.4 Future Work

i) There are many factors which complicate the interpretation of results from studies of aromatherapy massage in intensive care which include the vast number of different essential oils used, different massage procedures and different times for the recording of findings. Weinrich et al (1999) listed key areas that need to be addressed when undertaking research into aromatherapy. These include procedures used for massage (type of massage used, part of body massaged, length of massage) and analyses that control for the pre-massage level variable of interest They also suggested that valid research variables should be used which focus on concepts and have an impact on health, such as agitation, immune status and pain. It could be argued that using the wrong parameter or using an ineffective massage technique may overlook any therapeutic effects.

ii) Another variable that would merit further investigation is the type of essential oil used. The dose is important, including the body mass of the person receiving the essential oil and these should be tailored to each other. The type of essential oil used is important and in order to investigate the effects of these, single oils should be used.

Zinovieff (1999) pointed out that synthetic and low-grade essential oils have little or no therapeutic effect. He suggested that pure, high grade organically grown oils should be used which have been unadulterated and therefore have retained their therapeutic qualities. Zinovieff (1999) pointed out that few studies have demonstrated an effect with essential oils because they have used poor quality oils. There is however no evidence to quantify his theory.

In relation to patient numbers and the sample size of future studies, three main areas for consideration are proposed:

a) Future studies should use a maximum of two groups for comparison in an attempt to increase sample size. Larger studies are needed which examine one intervention to increase the power of statistical calculations. A greater sample size could have been achieved in this study by choosing one therapy ie massage or aromatherapy massage and having two groups instead of three with 75 patients in each group.
b) Studies should use a single essential oil instead of blends of oils so that the effects of each essential oil can be made more explicit.
c) The massage procedure should follow a protocol, which indicated massage movements, duration and frequency and future work should concentrate on finding the therapeutic time for administering the massage to demonstrate an effect. If these factors were controlled in other studies then comparison of results would be greatly enhanced.

iii) Investigating a slightly different population, such as patients who are not critically ill and unstable, for example those patients in a high dependency environment would possibly increase final comparisons due to patients being awake and therefore able to verbalise pre and post intervention outcomes. However there would be other problems such as short stay (2-3 days) of patients in a high dependency environment and the problem of obtaining consent from the consultant on each ward. Another suggestion would be not to impose the exclusion criteria at every massage time. This study found that the interventions did not increase patient's instability and therefore in a future study all patients admitted to the study that fulfilled inclusion criteria on entry to the study should not be excluded from any intervention. (ie massage).

iv) It would be useful to measure the effect of complementary therapies on long term ICU patients i.e. patients who are in ICU for longer than two weeks. This group of patients may benefit the most from massage only or aromatherapy massage as they are in ICU for a period of up to six weeks and it may help them to feel more relaxed, help to relieve joint and muscle stiffness and enhance their mood by feeling less anxious and depressed. It may be appropriate to undertake some case study research with this group of patients.

v) Future research to evaluate the use of complementary therapies in relation to the reduction in the quantity of analgesic and anaesthetic drugs utilised would be helpful. Research should demonstrate a cost analysis of the effects. Cost implications for a reduction in drug costs and a reduction in patient bed days (cut by a decline in side effects from drugs). Future work should also demonstrate any side effects from essentials oils.

vi) It would be useful to determine the effects of massage only or aromatherapy massage on sleep patterns and to determine any difference in patient outcomes if the intervention is given when the patient is sedated or awake.

vii) An easily accessible group to investigate with regards to ICU, which may produce more complete data sets, would be the next of kin or partner of the patient in ICU. It would be interesting to determine the effects of massage and aromatherapy massage on their levels of stress and anxiety and whether it was beneficial in helping them to cope with their experiences of a close relative being critically ill. It would be possible to follow relatives from ICU to the ward to home in order that massages could continue for a longer period of time. It is important to undertake more qualitative work to determine the patients', relatives and professionals views of massage only or aromatherapy massage and their effects. Patients, relatives and staff may suggest that using massage only or aromatherapy massage increases stress by adding another dimension to care.

viii) It would be interesting to determine the effects of recruiting patients (who are unable to consent to take part) into research studies by utilising their next of kin and the issues of gaining informed consent. It would be fascinating to compare which patients would have agreed with their next of kin's decision to be part of a research study, with those who would not have given consent had they been able to. It would be valuable to examine the psychological effects of giving informed consent to be part of a research study on the next of kin and the subsequent effects on the patients when they awake to find they are part of a study. The reasons as to why next of kin give consent for their loved ones to be part of a research study would be useful. It is very stressful asking patients' next of kin permission to be part of a research study, when they are already finding it difficult to cope with the grave situation and further work in this area would be useful when undertaking any research using patients who are unable to consent to be part of a study.

5.5. Limitations of the study

- The study was limited to an analysis involving patients who had received only two interventions (massages or aromatherapy massage). There is a possibility that more massages may have had a greater effect (Wilkinson et al 1999), but it was difficult to test this theory as a maximum of two consecutive massages were used in this study to standardise the sample and to reduce the problems of following patients to the wards. Patients may have required more than two interventions to demonstrate any beneficial effects, therefore suggesting that there may be a cumulative effect of massage or aromatherapy massage.
- There was a large patient loss between the first and second massage due to patients recovering and being discharged to the ward environment. This accounted for 37% (n=39) patients. The large loss from this study may have been overcome by following patients up once they had left the ICU. This was discussed at the planning phase of the study but was decided that it would be impossible to follow up patients on the wards to continue massages, due in main to other factors affecting the research, such as requiring consent from many other consultants and ward staff, and each ward environment being different and not being controlled. The large numbers of patients lost from the sample compromised the sample size utilised within the study, and this has led to some tentative conclusions being made based on a reduced sample. It

would have been more useful to study one experimental group to increase sample size and therefore the power of the results. In a future study it would be useful to include all patients even if they were cardiovascular unstable as the interventions did not appear to affect patients cardiovascular status.

- Intention to treat analysis was not used within this study due to the large patient loss from the study groups. Future studies need to consider whether such an approach should be incorporated.

- The use of the life events inventory to assess the amount of stress in each individual's life (as a pre-treatment variable) in order to compare HAD and SF36 scores (post-treatment), was not a satisfactory measure to use. The diverse scores that were collected from patients demonstrated this. It was also noted that if a patients' next of kin completed the inventory they expressed that they were not sure if they had completed it correctly and were unsure about some aspects of life stressors relating to their next of kin. It may have been more appropriate not to measure this aspect but to rely on the use of antidepressant or anxiolytic medication on admission as an indicator of any underlying problems. There are no validated tools specifically for use in patients who are unable to complete a pre-study questionnaire.

- The pain scale developed for use in this study was not sensitive enough to monitor patients' pain levels at the time around the massage. Most patients scores demonstrated a 'floor effect' and focused around score two (no pain). As patients were on continual infusions of analgesia and they were sedated it was difficult to measure any fluctuations in pain. Due to the nature of their critical illness it is necessary to maintain patients in a steady / stable status quo with the resultant effect of limited changes in analgesia and little changes in patients perception of pain.

- The sedation score developed to use in this study was not sensitive enough to measure slight changes in the level of patients' sedation. Also patient sedation does not change dramatically unless it is required to do so clinically (i.e. to sedate a patient or to wake a patient up). Some of the problems with the sedation scale may be due to the times when recordings were made. The sedation score was recorded hourly and within this time frame the patient can be at more than one level. Staff were asked to select the worst level during that time frame. Further development is required for this scale.

- Many patients encountered problems when completing the SF36 quality of life questionnaire. Many were unable to answer questions about levels of activity as they had been in an ICU and unable to undertake many activities. However patients recovering from a critical illness require a short and simple questionnaire to complete. The Profile of Mood States (McNair et al 1981) may have been a useful measure to use because although it consists of 65 emotions to rate, it can be divided into shorter subscales for the emotions investigated and shows good specificity (Fallowfield 1990). It is costly and time consuming to consider the development of new measurement tools.

- In order to study the same group of patients more closely, it would be necessary to undertake a case study approach to examine the longer-term ICU patients that may have had difficulty weaning from the ventilator and may not be unstable. It would then be possible to examine the relationship between the patients and therapist and the effect of more than one massage.

5.6 Summary

The use of massage only and aromatherapy massage have been increasingly utilised within healthcare (Carruthers 1992,Walsh 1996, Watson 1997, Brett 1999) with little evidence to support claims regarding their effectiveness. However the public have continued to demonstrate a desire to use these therapies both within and outside the NHS (Ernst and White 2000, Furnham 2000). It is important to substantiate claims regarding the use of complementary therapies in order to provide an evidence-based service and to enhance their status and regard in scientific circles. Continued efforts to raise clinicians' awareness about the uses of complementary therapies at national and local level through seminars and conferences would help to remove the stigma associated with these therapies.

This innovative study was unique in the manner it approached the use of massage and aromatherapy massage. It has addressed some of the problems of scientific credibility by utilising a stringent experimental approach. Practitioners of complementary therapies have argued that there are vast gaps in the research methodologies employed because they are inappropriate to this area of work. However, many complementary therapy practitioners do not have the necessary skills to undertake research to evaluate their effectiveness.

It is important to divert money into collaborative complementary therapy studies to enhance the amount of funding available to this area whilst their effectiveness is being determined instead of many small studies all occurring independently. This may also assist the development of research skills in those complementary therapy practitioners to enable them to be involved in credible scientific research. A collaborative approach will enable valid and valuable evidence to be produced by those using it, to allow access for everyone and to facilitate implementation into practice if outcomes are favourable. Complementary therapies will probably have a role to play in the future healthcare system (House of Lords Science and Technology Committee 2000). However, some of the benefits and uses of theses therapies have only recently been identified and tested in research studies. It is essential that collaboration of interested groups, such as the Royal College of Nursing (RCN), the Complementary Therapies Council and the Centre for Complementary Therapies take place in order that practice can continue to be informed, areas for research can be developed and consequently related healthcare is based upon sound clinical evidence that is cost effective. These groups can also act as support and guidance forums to aid medical and nursing staff that wishes to become involved in complementary therapies.

Within the scope of nursing the use of massage and aromatherapy has become one of the most commonly used complementary therapies (NHS Confederation 1998), but without the research evidence to base clinical practice upon, it is difficult to continue to provide the service in the increasingly accountable and liable National Health Service.

There was limited statistical evidence from this study to suggest that there are some benefits to using massage and aromatherapy massage compared to a no intervention group (control). This first major study tackling these issues has been undertaken and it can be used as a piece of primary research to build upon and for other work to be undertaken, taking into account the points raised within this study.

This study has been able to contribute to the existing body of knowledge substantially by highlighting many of the problems associated with CAM research that have not been exposed by the many small and isolated studies which have so far been undertaken. This study had demonstrated that the used of RCTs in massage and aromatherapy massage is a useful methodology to use and that it is possible to show some effects of these therapies by doing this.

The comprehensive literature review has made explicit the differences between studies and highlighted discrepancies within the current research evidence. The tables of research studies demonstrated that many different methods of undertaking research in massage and aromatherapy massage have been used and this has prevented comparison of the outcomes. Problems have included different times used to take outcome measurements, different massage techniques, different people used to undertake the massage, different lengths of times for the massage and different reasons for undertaking the massage or aromatherapy massage. Tabulating all current studies in this way has exposed the unorganised and erratic nature of massage and aromatherapy massage research. However it has also enabled these important areas to be taken into consideration in future work and for recommendations to be given.

This work has led to the production of two main areas to be considered for future work in massage and aromatherapy massage

1) Strict RCT methodology should be utilised, which should consider all elements of the research methodology including reason for massage, length of massage, number of massages, who will perform the massage and where it will be undertaken, the times of the outcome measurements.

2) Case study/ action research should also be undertaken, without strict controlled conditions but with each therapy tailored to each individual patient, and measuring many different outcomes that may not be clear at the outset, in order to explore unidentified and different effects of massage and aromatherapy.

6 CONCLUSIONS

This study should be utilised as a primary piece of research on which to base future studies. A larger body of knowledge is required to increase the available research so that care can be evidence based. There needs to be more research to demonstrate the effectiveness of complementary therapies in ICU. The research methodology should be dictated by the research question. The use of triangulation methodology to incorporate different and more appropriate research methodologies is vital and can be developed as part of the research.

1. Patients who received an aromatherapy massage demonstrated a significantly decreased mean diastolic blood pressure four hours after a second consecutive massage compared to patients who had received no

intervention. There were no differences in heart rate and systolic blood pressure between the groups.

2. The quantity of analgesic drugs used by patients who received aromatherapy massage was significantly less than those patients who did not receive any intervention on the day following the aromatherapy massage.

3. The quantity of hypnotic drugs required by all groups (two treatment and one control) of patients did not demonstrate any differences. More patients who received an aromatherapy massage were categorised as being asleep one hour after the first aromatherapy massage, compared to patients in the control group.

4. There were no differences in anxiety, depression and quality of life between patients who received massage only, aromatherapy massage or no intervention.

This study has made a substantial contribution to the small existing body of knowledge, especially with regard to its methodological approach and has shown that randomised controlled trial methodology is a useful tool to use when examining aromatherapy massage, dependent on the research question.

REFERENCES

Aldridge D (1989) Research Strategies in a hospital setting: the development of appropriate methods. Complementary Medical Research 3(3), 20-24.

Aylard PR, Gooding JH, McKenna PJ and Snaith RP (1987) A validation study of three anxiety and depression self assessment scales. Journal of Psychosomatic Research 31, 261-268.

Anderson E and Anderson P (1987) General Practitioners and Alternative Medicine. Journal of the Royal College of General Practitioners 37, 52-55.

Anderson J, Sullivan F and Underwood T (1990) The Medical Outcomes Study Instrument (MOSI) - use of a new health status measure in Britain. Family Practice 7, 205-218.

Anthony HM (1988) Why measure outcomes? Complementary Medical Research 2 (3) 1-11.

Armstrong F (1986) Aromatherapy. Professional Nurse 1(II), 306.

Armstrong F (1991) Scenting relief. Nursing Times 87(10, 6 March), 52-53.

Ashton J (1984) In your hands. Nursing Times 80(19, 9 May), 54.

Aurell J and Elmqvist D (1985) Sleep in the surgical intensive care unit: continuous polygraphic recording of nine patients receiving post-operative care. British Medical Journal 290, 1029-1032.

Avis A (1999) Aromatherapy. Nursing Standard 13(24, 3-9 March), 14-15.

Baker S (1999) Aromatherapy and essential oil safety. International Journal of Alternative and Complementary Medicine 17(5) May, 26-27.

Balacs T (1991) Research reports. International Journal of Aromatherapy 3 (1) 6-8.

Balacs T (1992) Research reports. International Journal of Aromatherapy 4 (1) 28-29.

Baldwin S (1991) Complementary Health. Nursing 4 (46) 15-17.

Bannerman RH, Burton J, Wen-Chieh C (1983) Traditional medicine and health care coverage: a reader for health administrators and practitioners. WHO (Geneva, Switzerland).

Barr JS and Taslitz N (1970) The influence of back massage on autonomic functions. Physical Therapy 50(12) 1679-1691.

Basnyet J (1999) The effect of aromatherapy treatment on raised arterial blood pressure - pilot study. Positive Health 39, April 20-23.

Bauer WC and Dracup KA (1987) Physiological effects of back massage in patients with acute myocardial infarction. Focus on Critical Care 14 (6) December, 42-46.

Bay F (1995) Complementary therapies - just another task? Complementary Therapies in Nursing and Midwifery 1, 34-36.

Bell L (1993) Assessing the effects of aromatic oils. Nursing Times April 28 89 (17) 66.

Bellis P (1996) Tense Times. Liverpool Echo (16 July), 6.

Bieri D, Reeve RA, Champion GD, Addicoat L, Ziegler JB (1990) The faces pain scale for the assessment of the severity of pain experienced by children: development and initial validation and preliminary investigation for ratio scale properties. Pain 41, 139-150.

Biley FC and Freshwater D (1999) Trends in nursing and midwifery research and the need for change in complementary therapy research. Complementary Therapies in Nursing and Midwifery, August 5 (4), 99-102.

Bion JF (1988) Sedation and Analgesia in the Intensive Care Unit. Hospital Update 14, 1272-1286.

Bion JF and Ledingham I (1987) Sedation in Intensive Care - a postal survey. Intensive Care Medicine 13, 215-216.

Booth B (1993) Healthy Alternatives? Nursing Times 89 (17) 34-35.

Brazelton TB (1983) Neonatal behavioural assessment scale. Spastic International Medical Publications, London.

Brazier JE, Harper R, Jones NMB, O'Cathain A, Thomas KJ, Usherwood T, Westlake L (1992) Validating the SF-36 health survey questionnaire: new outcome measures for primary care. British Medical Journal 305, 160-164.

Brett H (1999) Aromatherapy in the care of older people. Nursing Times 95 (33) 18 August), 56-57.

Brewer M (1985) To sleep or not to sleep: the consequences of sleep deprivation. Critical Care Nurse 5, 35.

Brewin CR and Bradley C (1989) Patient preferences and randomised clinical trials. British Medical Journal 299, 313-315.

British Medical Association (1986) Report on the board of science and education on Alternative Therapy. British Medical Association, London.

British Medical Association (1993) Complementary Medicine: new approaches to good practice. Oxford University Press, Oxford.

Brooker DJR, Snape M, Johnson E, Ward D, Payne M (1997) Single case evaluation of the effects of aromatherapy and massage on disturbed behaviour in severe dementia. British Journal of Clinical Psychology 36, 287-296.

Brook RH, Ware JE, Roger WR, Keller EB, Davies A, Donald CA, Goldberg GA, Lohr KN, Masthay PC, Newhouse JP (1983) Does free care improve adults' health? Results from a randomised controlled trial. New England Journal of Medicine 309, 1426-1434.

Brownfield A (1998) Aromatherapy in arthritis: a study. Nursing Standard 13 (5) 21-27 October, 34-35.

Bruynzeel DP, van Ketel WG, Young E, van Joost TH and Smeenk G (1992) Contact sensitisation by alternative topical medicaments containing plant extracts. Contact Dermatitis 27, 278-279.

Buckle J (1992) A randomised double blind aromatherapy trial to assess the therapeutic effects of two essential oils of lavender on the emotional and behavioural stress of patients nursed in an ITU following open heart surgery. B.Phil Thesis, Exeter University, Bath.

Buckle J (1992) Which lavender oil?. Nursing Times 88 (32) 54-55.

Buckle J (1993) Aromatherapy: does it matter which lavender essential oil is used? Nursing Times 89 (20) 19 May, 32-35.

Budd S and Mills S (2000) Professional Organisation of Complementary and Alternative Medicine in the United Kingdom 2000. A second report to the Department of Health. University of Exeter, Exeter.

Burns E and Blamey C (1994) Using aromatherapy in childbirth. Nursing Times 90 (9) 2 March, 54-60.

Burns E, Blamey C, Ersser SJ, Barneston L, Lloyd AJ (2000) An investigation into the use of aromatherapy in intrapartum midwifery practice. Journal of Alternative and Complementary Medicine 6 (2) April, 141-147.

Byass R (1988) Soothing body and soul. Nursing Times 84 (24) 15 June, 39-41.

Byrne C (1992) Research methods in complementary therapies. Nursing Standard 6 (50) 2 Sept, 54-56.

Campbell D and Stanley J (1963) Experimental and quasi-experimental designs for research. Houghton Mifflin Company, Boston.

Canavan T (1984) The psychobiology of sleep. Nursing Standard 2 (23) 682-683.

Cannard G (1995) On the scent of good night's sleep. Nursing Standard 9 (34) 17-23 May, 21.

Cannard G (1996) The effect of aromatherapy in promoting relaxation and stress reduction in a general hospital. Complementary Therapies in Nursing and Midwifery 2, 38-40.

Canter DA (1987) Research agenda for holistic therapy. Complementary Medical Research 2 (1) 104-116.

Canter DA (1988) How do we know that it works? Therapeutic outcome as negotiation. Complementary Medical Research 2 (3) 98-106.

Carola R, Harley J, Noback C (1990) Human Anatomy and Physiology. McGraw Hill, New York.

Carruthers A (1992) A force to promote bonding and well-being: therapeutic touch and massage. Professional Nurse February 297-300.

Casey RL, Masuda M and Holmes TH (1967) Quantitative study of recall of life events. Journal of Psychosomatic Research 11, 239.

Cawthorn A (1991) Aromatherapy at the Devonshire Royal Hospital: The way forward. Unpublished thesis, Stockport, Tameside and Glossop College of Nursing.

Cawthorn A (1995) A review of the literature surrounding the research into aromatherapy. Complementary Therapies in Nursing and Midwifery 1 (4) 118-121.

Cerrato PL (1998) Aromatherapy: Is it for real? Registered Nurse 61 (6) June 51-52.

Chabrier C (1987) Massage. Health Visitor 60 June 200.

Chalmers I, Keirse MJNC, Enkin M (Eds) (1989) Effective Care in Pregnancy and Childbirth. Oxford University Press, Oxford.

Chalmers I, Hetherington J, Elbourne D, Keirse MJNC, Enkin M (1989) Materials and methods used in synthesising evidence to evaluate the effects of care during pregnancy and childbirth. In: Chalmers I, Enkin M, and Keirse MJNC (Eds). Effective Care in Pregnancy and Chilbirth. Pgs 39-65. Oxford University Press, Oxford.

Ching M (1998) Complementary therapies: research, education and practice in nursing. Contemporary Nurse: A Journal for the Australian Nursing Profession 7 (4) December 173-179.

Ching M (1999) Contemporary therapy: aromatherapy in the management of acute pain? Contemporary Nurse: A Journal for the Australian Nursing Profession 8 (4) December 146-151.

Clarke DA (1999) Advancing my health care practice in aromatherapy. Australian Journal of Holistic Nursing 6 (1) April 32-38.

Cohen J (1960) A co-efficient of agreement for nominal scales. Educational and Psychological Measurement 20, 37-46.
Colditz GA, Miller JN, Mosteller F (1989) How study design affects outcomes in comparisons of therapy. 1:medical. Statistics in Medicine 8, 441-454.

Colditz GA, Miller JN, Mosteller F (1989) How study design affects outcomes in comparisons of therapy. Statistics in Medicine 8, 441-454.

Cole A, Shanley E (1998) Complementary therapies as means of developing the scope of professional nursing practice. Journal of Advanced Nursing 27 (6) June 1171-1176.

Consumers Association (1986) Magic or Medicine? Which, October 443-447.

Consumers Association (1992) Regulation of practitioners of non-conventional medicine. Consumers Association, London.

Cook S and Palma O (1989) Diprivan as the sole sedative agent for prolonged infusion in intensive care. Journal of Drug Development 2, 65-67.

Cooke B and Ernst E (2000) Review: aromatherapy massage is associated with small, transient reductions in anxiety. British Journal of General Practitioners 50 June, 493-496.

Cooper E (1995) The use of aromatherapy in palliative care for patients with advanced cancer. The Aromatherapist 2 (3), 27-36.

Corley MC, Ferriter J, Zeh J and Gifford C (1995) Physiological and Psychological Effects of Back Rubs. Applied Nursing Research 8 (1), 39-43.

Corner J, Cawley N and Hilderbrand S (1995) An evaluation of the use of massage and essential oils on the well-being of cancer patients. International Journal of Palliative Nursing 1 (2) 67-73.

Coward R (1989) The whole truth: the myth of alternative health. Faber, London.

Coxon A (1991) Prescribing Aromatherapy. Aromatherapy Quarterly, Winter 31, 9-12.

Crowne DP and Marlowe D (1960) A new scale of social desirability independent of psychopathology. Journal of Consulting Psychology 24 (3) 43-49.

Crowther D (1991) Complementary therapy in practice. Nursing Standard 5 (23 February) 25-27.

Cullen DJ, Civetta JM, Briggs BA and Ferrara LC (1974) Therapeutic intervention scoring system: a method for quantitative comparison of patient care. Critical Care Medicine 2 (2) 57-60.

Dale A and Cornwell S (1994) The role of lavender oil in relieving perineal discomfort following childbirth: a blind randomised clinical trial. Journal of Advanced Nursing 19, 89-96.

Dannert F, Hedstrand U and Holmdahl M (1975) Patient Material in Multidisciplinary Intensive Care Units. Acta Anaesthesiol Scand 57, 64-70.

De Haes JCJM, Knippenberg FCE and Neijt JP (1990) Measuring psychological and physical distress in cancer patients: structure and application of the Rotterdam Symptom Checklist. British Journal Cancer 62, 1034-1038.

Dickson N (1996) Critical Masses. Nursing Times 92 (13) 27 March 62.

Diego MA, Jones NA, Field T, Hernandez-Reif M, Schanberg S, Kuhn C, McAdam V, Galamaga R and Galamaga M (1998) Aromatherapy positively affects mood, EEG patterns of alertness and math computations. International Journal of Neuroscience 96 217-224.

Downer K (1999) Safety is of the essence. Nursing Times 95 (7) 17 February 14-15.

Dunn C, Sleep J and Collett D (1995) Sensing improvement: An experimental study to evaluate the use of aromatherapy, massage and periods of rest in an intensive care unit. Journal of Advanced Nursing 21, 34-40.

Eisenberg DM, Kessler RC, Foster C, Norlock FE, Calkins DR and Delbanco TL (1993) Unconventional medicine in the United States. New England Journal of Medicine 328 246-252.

Emly M (1993) Abdominal Massage. Nursing Times 89 (3) 20 January 34-36.

Ernst E (1997) Evidence-based complementary medicine. Complementary Therapies in Nursing and Midwifery 3, 42-45.

Ernst E and White A (2000) The BBC survey of complementary medicine use in the UK. Complementary Therapies in Medicine 8 (1) 32-36.

Ersser S (1995) Complementary therapies and nursing research: issues and practicalities. Complementary Therapies in Nursing and Midwifery 1, 44-50.

Ersser S, Bentley T, Chappell S, Taylor H, Wade S, Walsh R and Wiles A (1998) Sleep of older people in nursing care settings and the impact of back massage on sleep. A pilot study. Oxford Centre for Health Care Research and Development. Oxford Brookes University. Report no.2.

Ersser S,Wiles A, Taylor H, Wade S, Walsh R and Bentley T (1999) Measuring the sleep of older people: Tool development and use in the evaluation of therapeutic massage. Nursing Times *Research* 4 (1) 55-64.

European Commission (1989) Council Directive 89/48/EC. Official Journal European Community L19, 16-23.

European Commission (1990) Proposal for a council directive on the liability of suppliers of services. Presented to the commission of the EC. Com (90) 482.Final-syn 308

Evans B (1995) An audit into the effects of aromatherapy massage and the cancer patient in palliative and terminal care. Complementary Therapies in Medicine 3, 239-241.

Fakouri C and Jones P (1987) Relaxation RX: slow stroke back rub. Journal of Gerontological Nursing 13 (2) 32-35.

Fallowfield L (1990) The Quality of Life. The Missing Measurement in Health Care. Human Horizons Series. Souvenir Press. London.

Farrow J (1990) Massage Therapy and Nursing Care. Nursing Standard 4 (17) 17 January) 26-28.

Ferrell-Torry AT and Glick OJ (1993) The use of therapeutic massage as a nursing intervention to modify anxiety and the perception of cancer pain. Cancer Nursing 16 (2) 93-101.

Field T, Morrow C, Valdeon C, Larson S, Kuhn C and Schanberg S (1992) Massage reduces anxiety in child and adolescent psychiatric patients. Journal of the American Academy of Childhood and Adolescent Psychiatry 31(1) 125-131.

Field T, Scafidi F and Schanberg S (1987) Massage of preterm newborns to improve growth and development. Pediatric Nursing November-December 13 (6) 385-387.

Field TM, Sunshine W, Hernandez-Reif M, Quintino O, Schanberg S, Kuhn C and Burman I (1997) Massage Therapy Effects on Depression and Somatic Symptoms in Chronic Fatigue Syndrome. Journal of Chronic Fatigue Syndrome 3 (3) 43-51.

Field T, Peck M, Krugman BS, Tuchel T, Schanberg S, Kuhn C and Burman I (1998) Burn injuries benefit from massage therapy. Journal of Burn Care and Rehabilitation May/June 241-244.

Fisher P and Ward A (1994) Complementary medicine in Europe. British Medical Journal (309) 9 July 107-111.

Fitter MJ and Thomas KJ (1997) Evaluating complementary therapies for use in the National Health Service: 'Horses for Courses'. Part 1: The design challenge. Complementary Therapies in Medicine 5, 90-93.

Fraser J and Ross Kerr J (1993) Psychophysiological effects of back massage on elderly institutionalised patients. Journal of Advanced Nursing 18, 238-245.

Fromant P (1991) Let me rub it better. Nursing 4 (46) 18-19.

Fulder SJ and Munro RE (1985) Complementary Medicine in the United Kingdom: patients, practitioners and consultants. Lancet 7 September 542-545.

Furnham A (2000) How the public classify complementary medicine: a factor analytic study. Complementary Therapies in Medicine 8, 82-87.

Gassert CA (1990) Reliability and validity of physiological measures. Critical Care Nursing Quarterly 12, 17-20.

Gates B (1994) The use of complementary and alternative therapies in health care: a selective review of the literature and discussion of the implications for nurse practitioners and health care managers. Journal of Clinical Nursing 3, 43-47.

Gattefosse R (1993) Gattefosses Aromatherapy. Saffron Walden. The CW Daniel Company Limited, Essex.

Gibbons E (1998) Can aromatherapy replace pre-medication? British Journal of Theatre Nursing 8 (5) August 34-36.

Goldberg D (1992) General Health Questionnaire (GHQ-12). NFER-Nelson, Windsor.

Gow GL (1995) Influence of sedation regimes: effects on recall following treatment in an ICU. British Journal of Intensive Care April 112-116.

Greenberg AG, McClure DK, Janus CA and Stubbs JA (1978) Nursing Intervention Scoring System: A concept for management, research and communication. Lecture notes in medical informatics 1, 729-738.

Groer M, Mozingo J, Droppleman P, Davis M, Jolly ML, Boynton M, Davis K and Kay S (1994) Measures of Salivary Sectretory Immunoglobulin A and State Anxiety After a Nursing Back Rub. Applied Nursing Research 7 (1) 2-6.

Halpern S (1985) What the public thinks of the NHS. Health and Social Services Journal (6) 6 June 702-704.

Hand DJ and Taylor CC (1996) Multivariate Analysis of Variance and Repeated Measures. A practical approach for behavioural scientists. Chapman and Hall, London.

Hanse M (1990) Points of view. Nursing Standard 4 (48) 43.

Hardy M (1991) On the scents of a good nights sleep. Nursing Standard 9 (34) 21.

Hardy M (1991) Sweet Scented Dreams. International Journal of Aromatherapy 3 (1) 12-13.

Hayes J and Cox C (1999) Immediate effects of a five minute foot massage on patients in critical care. Intensive and Critical Care Nursing 15 (2) 77-82.

Hayes J and Cox C (2000) Immediate effects of a five minute foot massage on patients in critical care. Complementary Therapies in Nursing and Midwifery 6, 9-13.

Henderson V and Nite G (1978) Principles and practice of nursing. Macmillan, New York.

Hewitt D (1992) Massage with lavender oil lowered tension. Nursing Times 88 (25) 8.

Hill C (1993) Is massage beneficial to critically ill patients in intensive care units? A critical review. Intensive and critical care nursing 9, 116-121.

Hjortso E, Buch T, Ryding J, Lundstrom K, Bartram P, Dragsted L and Qvist J (1992) The nursing care recording system. A preliminary study of a system for assessment of nursing care demands in the ICU. Acta Anaesthesiol Scand 36, 610-614.

Holmes TH and Rahe RH (1967) The social readjustment rating scale. The Journal of Psychosomatic Research 11, 213.

Holmes P (1986) Fringe Benefits. Nursing Times 82 (22) 20-22.

Horne J (1983) Human sleep and tissue restitution: some qualifications and doubts. Clinical Science 65, 569-578.

House of Lords Select Committee (2000) Complementary and Alternative Medicine. Sixth Report.

Howdyshell C (1998) Complementary therapy: aromatherapy with massage for geriatric and hospice care, a call for an holistic approach. Hospice Journal 13 (3) 69-75.

Hudak C, Gallo B and Benz J (1990) Critical Care Nursing; A Holistic Approach. 5th ed. JB Lippincott Company, Philadelphia.

Hudson R (1994) Lavender oil aids relaxation in older patients (Short Report). Nursing Times 90 (30) 12.

Hudson R (1996) The value of lavender for rest and activity in the elderly patient. Complementary Therapies in Medicine 4 (1) 52-57.

Hulme J, Waterman H and Hillier VF (1999) The effect of foot massage on patients' perception of care following laparoscopic sterilisation as day case patients. Journal of Advanced Nursing 30 (2) 460-468.

Jackson A (1995) Alternative Update. Nursing Times 91(8) 61.

Jadad AR (2000) Randomised Controlled Trials. A users guide. BMJ Books, Plymouth.

Jager W, Buchbauer G, Jirovetz L and Fritzer M (1992) Percutaneous absorption of lavender oil from a massage oil. Journal of Society of Cosmetic Chemists 43, 49-54.

Jamerson P, Scheibmeir M, Bott M, Crighton F, Hinton R and Cobb A (1996) The experiences of families with a relative in the intensive care unit. Heart and Lung The Journal of Acute and Critical Care 25 (6) 467-474.

Janine Bell CM (1987) How can individual practitioners contribute to research? Complementary Medical Research 2 (2) 168-174.

Jenkinson C, Coulter A and Wright L (1993) Short Form 36 (SF-36) health survey questionnaire. Normative data for adults of working age. British Medical Journal 306, 1437-1440.

Jenkinson C, Ziebland S, Fitzpatrick R, Mowat A and Mowat A (1993) Hospitalisation and its influence upon results from health status questionnaires. International Journal of Health Sciences, .

Joachim G (1983) How to give a great foot massage. Geriatric Nursing 4, 28-29.

Joachim G (1983) Step by step massage techniques. Canadian Nurse 4, 32-35.

Jori A et al (1969) Effects of essential oils on drug metabolism. Biochemical Pharmacology 18, 2081-2085.

Jose Closs S (1988) Assessment of sleep in hospital patients: a review of methods. Journal of Advanced Nursing 13, 501-510.

Kaada B and Torsteinbo O (1989) Increase of plasma B endorphins in connective tissue massage. General Pharmacology 20 (4) 487-489.

Kane RL, Olsen D, Leymaster C, Woolley FR and Fisher FD (1974) Manipulating the patient. A comparison of the effectiveness of physician and chiropractor care. Lancet 1 June 29, 1333-1336.

Karlowski TR, Chalmers TC, Frenkel LD, Kapikian AZ, Lewis TL and Lynch JM (1975) Ascorbic acid for the common cold: a prophylactic and therapeutic trial. Journal of American Medical Association 231, 1038-1042.

Keene AR and Cullen DJ (1983) Therapeutic Intervention Scoring System: Update 1983. Critical Care Medicine 11(1) 1-3.

Kimber L (1998) How did it feel? An informal survey of massage techniques in labour. The Practising Midwife 1, 12th December, 38-41.

Kingman S (1991) The sweet smell of less stress. Independent on Sunday 5th May.

Kirkwood BR (1988) Essentials of Medical Statistics. Blackwell Scientific Publications, Oxford.

Kirshbaum M (1996) Using massage in the relief of lymphoedema. Professional Nurse, January 11 (4) 230-232.

Kite SM, Maher EJ, Anderson K, Young T, Young J, Wood J, Howells N and Bradburn J (1998) Development of an aromatherapy service at a cancer centre. Palliative Medicine 12 (3) 171-180.

Kleijnen J, Gotzsche P, Kunz RA, Oxman AD and Chalmers I (1998) So whats so special about randomisation? In: Chalmers I and Maynard A (eds): Non-Random Reflections on Health Services Research. British Medical Journal, London.

Knasko SC (1992) Ambient odor effects on creativity, mood and perceived health. Chemical Senses 17 (1) 27-35.

Knaus WA, Draper EA, Wagner DP and Zinnerman JE (1985) APACHE 11: a severity of disease classification system. Critical Care Medicine 13, 818-829.

Kovar KA, Gropper B, Friess D and Ammon HP (1987) Blood levels of 1,8-cineole and locomotor activity of mice after inhalation and oral administration of rosemary oil. Planta Medica 53 (4) 315-318.

Labyak SE and Metzger BL (1997) The effects of effleurage backrub on the physiological components of relaxation: a meta-analysis. Nursing Research 46 (1) Jan/Feb, 59-62.

Laing A (1992) The applicability of a new sedation scale for intensive care. Intensive and Critical Care Nursing 8, 149-152.

Landis JR and Koch GG (1977) The measurement of observer agreement for categorical data. Biometrics 33, 159-174.

Le Boyer F (1976) Loving Hands: The traditional art of baby massage. Knopf. New York.

Ledingham I and Watt I (1983) Influence of sedation on mortality in multiple trauma patients. Lancet i, 1270.

Leibrich J (1990) Measurement of efficacy: a case for holistic research. Complementary Medical Research 2 (1) 5-9.

Lennox M (1997) Aromatic Mixer. Elderly Care 9 (1) 36.

Lindsay WR, Pitcaithly D, Geelan N, Buntin L, Broxholme S and Ashby M (1997) A comparison of the effects of four therapy procedures on concentration and responsiveness in people with profound learning disabilities. Journal of Intellectual Disability Research 41(3) June, 201-207.

Lis-Balchin M, Deans S and Hart S (1997) A study of the changes in the bioactivity of essential oils used singly and as mixtures in aromatherapy. Journal of Alternative and Complementary Medicine 3, (3) Fall, 249-256.

Longworth JCD (1982) Psychophysiological effects of slow stroke back massage in normotensive females. Advances in Nursing Science 6, 44-61.

Macdonald K (1993) Orange blossom cure for heart patients. Daily Mail March 16th 40.

MacMahon S and Kermode S (1998) A clinical trial of the effect of aromatherapy on motivational behaviour in a dementia care setting using a single subject design. Australian Journal of Holistic Nursing 5 (2) October, 47-49.

Malstam J and Lind L (1992) Therapeutic intervention scoring system (TISS) - a method for measuring workload and calculating costs in the ICU. Acta Anaesthesiol Scand 36, 758-763.

Manley CH (1993) Psychophysiological effect of odor. Critical Reviews in Food Science and Nutrition 33 (1) 57-62.

Martin S (1991) Wheres the proof? Heres Health December, 36-38.

Mason P (1995) Critical Condition. Nursing Times 91(14) 5 April, 14-15.

McCorkle R (1981) Non-obtrusive measures in clinical nursing research. Cassell Ltd., London. Pages 20-26.

McGonigal K (1986) The importance of sleep and the sensory environment to critically ill patients. Intensive care nursing 2, 73-83.

McGourty H and Hotchkiss J (1993) Study Rules. Nursing Times 89 (36) 8 September, 42-45.

McGuire D (1988) Measuring Pain. In Frank-Stromberg M (Ed) Instruments for clinical nursing research (pgs 333-356) Norwalk, CT. Appleton and Lange.

McIntosh A (1989) Sleep deprivation in critically ill patients. Nursing 3 (35) 44-45.

McNair DM, Lorr M and Droppleman LF (1981) POMS - Profile of mood states. Educational and Industrial Testing Service, San Diego, CA.

Meade TW, Dyer S, Browne W, Townsend J and Frank AO (1990) Low back pain of mechanical origin: randomised comparison of chiropractic and hospital outpatient treatment. British Medical Journal (Clinical Research Ed.) 300, June 2, 1431-1437.

Meek S (1993) Effects of Slow Stroke Back Massage on Relaxation in Hospice Clients. IMAGE:Journal of Nursing Scholarships, Spring 25 (1) 17-21.

Melzack R (1987) The short form McGill Pain Questionnaire. Pain 30, 191-197.

Merriman HM (1981) The techniques used to sedate ventilated patients. Intensive Care Medicine 7, 217-224.

Michelsen D (1978) Giving a great back rub. American Journal of Nursing July, 1197-1199.

Mills S (1993) The development of the complementary medical professions. Complementary Therapies in Medicine 1, 24-29.

Miranda DR, Williams A and Loirat P (1990) Management of Intensive Care: guidelines for better use of resources. Kluwer Academic Publishers, Dordrecht.

Moore J, Phipps K and Marcer D (1985) Why do people seek treatment by alternative medicine? British Medical Journal 290, 5th January, 28-29.

MORI (1989) MORI Poll. The Times, 13th November.

Moser KM (1982) The alternative therapy controversy: facts are needed. Heart Lung 11 (3) 195-196.

Moysan A, Morliere P, Averbeck D and Dubertret L (1993) Evaluation of phototoxic risk associated with the use of photosensitisers in suntan preparations: application to tanning preparations containing bergamot oil. Skin Pharmacology 6 (4) 282-291.

Mulrow CD and Oxman AD (Eds.) (1997) Cochrane Collaboration Handbook. Issue 4 ed. The Cochrane Collabration, Oxford.

Murdaugh C (1986) Critique of the study design. In LRF Philips, A Clinicians guide to the critique and utilisation of nursing research. (203-236). Norwalk, C.T: Appleton Century-Crofts.

Murray J and Shepherd S (1988) Alternative or additional medicine? A new dilemma for the doctor. Journal of the Royal College of General Practitioners 38, 511-514.

Naganuma M, Hirose S, Nakayama Y (1985) A study of the phototoxicity of lemon oil. Archives of Dermatological Research 278 (1) 31-36.

National Health Service Confederation (1998) Complementary Medicine in the NHS, managing the issues.

Nisbett H and Norris W (1963) Objective measurement of sedation 11, A simple scoring system. British Journal Anaesthesia 35, 618-623.

Nuremberg Code (1949) Trials of war criminals before the Nuremberg Military Tribunals under Control Council Law. Washington DC: US Government Printing Office 2 (10) 181.

O'Byrne J (1990) The smell of success. Nursing Standard 4 (47) 15th August, 23.

Occhiuto F and Circosta C (1996) Antianginal and antiarrthymic effects of bergamottine, a furocoumarin isolated from bergamot oil. Phytotherapy Research 10, 6th September, 491-496.

Occhiuto F and Circosta C (1997) Investigations to charactise the antiarrythmic action of bergamottine, a furocoumarin isolated from bergamot oil. Pytotherapy Research 11, 6th September, 450-453.

Olleveant NA, Humphris G and Roe B (1998) A reliability study of the modified New Sheffield Sedation Scale. Nursing in Critical Care 3 (2) 83-88.

Olleveant NA, Humphris G and Roe B (1999) How big is a drop? A volumetric assay of essential oils. Journal of Clinical Nursing 8, 299-304.

Oswald I (1984) Good, Poor and Disordered Sleep. Sleep: An International Monograph, Update books, London. Pgs 18-24.

Papadopoulos A, Wright S and Ensor J (1999) Evaluational and attributional analysis of an aromatherapy service for older adults with physical health problems and carers using the service. Complementary Therapies in Medicine 7 (4) 239-244.

Passant H (1990) A holistic approach in the ward. Nursing Times 86 (4) 26-28.

Passant H (1991) A renaissance in nursing. Nursing 4 (25) 12-13

Paterson L (1990) Baby massage in the neonatal unit. Nursing 4 (23) 19-21.

Perry R and Dowrick CF (2000) Complementary medicine and general practice: an urban perspective. Complementary Therapies in Medicine 8, 71-75.

Pietroni J (1991) NHS funds GP massage clinic. Massage 3, 1.

Pietroni P (1992) Beyond the boundaries: Relationship between general practice and complementary medicine. British Medical Journal 305, 564-566.

Polit DF and Hungler BP (1989) Essentials of Nursing Research. Methods, Appraisal and Utilisation. Second Edition. JB Lippincott Company, London.

Price S (1993) Shirley Prices Aromatherapy Workbook. Understanding essential oils from plant to bottle. Thorsons, London.

Price S (1998) Using essential oils in professional practice. Complementary Therapies in Nursing and Midwifery 4, 144-147.

Rainbow C (1989) Monitoring the critically ill patient. Heinemann, London. Pgs 182-188.

Rankin-Box D (1991) Proceed with caution. Nursing Times 87 (45) 34-36.

Rankin-Box D (1992) European Developments in Complementary Medicine. British Journal of Nursing 1 (2) 103-105

Rankin-Box (1993) Innovation in Practice: complementary therapies in nursing. Complementary Therapies in Medicine 1, 30-34.

Rankin-Box D (1995) Competence in the clinical setting: issues in nursing practice. Complementary Therapies in Medicine 3, 25-27

Rankin-Box D (1997) Therapies in practice: a survey assessing nurses use of complementary therapies. Complementary Therapies in Nursing and Midwifery 3, 92-99

Reed L and Norfolk L (1993) Aromatherapy in Midwifery. International Journal of Alternative and Complementary Medicine, December, 15-17.

Reilly DT (1983) Young Doctors' views and on alternative medicine. British Medical Journal 287, 30th July, 337-339.

Rice R (1977) Neurophysiological development in premature infants following stimulation. Developmental psychology 13, 69-76.

Richards K (1998) Effect of a Back Massage and Relaxation Intervention on Sleep in Critically Ill Patients. American Journal of Critical Care 7 (4) 288-299.

Richards K, Gibson R and Overton-McCoy AL (2000) Effects of massage in acute and critical care. AACN Clinical Issues 11 (1) 77-96.

Richardson J (2000) The use of randomised controlled trials in complementary therapies: exploring the issues. Journal of Advanced Nursing 32 (2) 398-406.

Robins JL (1999) The science and art of aromatherapy. Journal of Holistic Nursing 17, 1st March, 5-17.

Roche PA, Taylor Reilly D and Boyd W (1987) Measurement in holistic medicine: a pilot study of global distress. Complementary Medical Research 2 (1) 19-32.

Royal College of Physicians (1990) Research Involving Patients; a Report of the Royal College of Physicians, January, London.

Rowan KM, Kerr JH, Major E, McPherson K, Short A and Vessey MP (1993) Intensive Care Society's APACHE 11 study in Britain and Ireland - 1: Variations in case mix of adult admissions to general intensive care units and impact on outcome. British Medical Journal 307, 972-981.

Ruiz-Canela M, Martinez-Gonzalez MA and Irala-Estevez J (2000) British Medical Journal, 320, 8th April, 1007-1008.

Rukholm E, Bailey P, Coutu-Wakulczyk G and Bailey WB (1991) Needs and anxiety levels in relatives of intensive care unit patients. Journal of Advanced Nursing 16 (8) 920-928.

Sackett DL (1979) Bias in analytical research. Journal of Chronic Diseases 32, 51-63.

Sackett DL (1991) Clinical Epidemiology: a basic science for clinical medicine. 2nd ed. Little Brown, Boston.

Saeki Y (2000) The effect of foot-bath with or without the essential oil of lavender on the autonomic nervous system: a randomised trial. Complementary Therapies in Medicine 8 (1) 2-7.

Salvage J (1990) The theory and practice of the 'new nursing'. Nursing Times 86 (4) 42-45.

Say B (1991) A panacea for all ills. Nursing Times 87 (15) 58-60.

Scafidi F, Field T, Schanberg S, Bauer CR, Tucci K, Roberts J, Morrow C and Kuhn CM (1990) Massage stimulates growth in pre-term infants: a replication. Infant behaviour and development 13, 167-188.

Schulz KF, Chalmers I, Hayes RJ and Altman D (1995) Empirical Evidence of Bias. Journal of American Medical Association 273, 408-412.

Scott E (1995) Complementary Therapies: Body and Soul. Nursing Standard 9 (37) 22-23.

Sims S (1986) Slow stroke back massage for cancer patients. Nursing Times. Occasional paper 82 (13) 47-50.

Slatyer MA, James OF, Moore PG and Leeder SR (1986) Costs, severity of illness and outcome in intensive care. Anaesthetic Intensive Care 14, 381-389.

Smith M (1990) Healing through touch. Nursing Times 86 (4) 31-32.

Snaith RP, Ahmed SN, Metha S and Hamilton M (1971) Assessment of the severity of primary depressive illness. Wakefield self-assessment depression inventory. Psychological Medicine 1, 143-149.

Spielberger CD, Gorsch RL, Lushene RE, Vagg PR and Jacobs GA (1983) Manual for the State-Trait Anxiety Inventory. Councelling Psychologists Press, Palo Alto, California.

Stevensen C (1994) The psychophysiological effects of aromatherapy massage following cardiac surgery. Complementary Therapies in Medicine 2 (1) 27-35.

Stevenson C. (1992) Orange Blossom Evaluation. The International Journal of Aromatherapy 4 (3) Autumn, 22-24.

Streiner DL and Norman GR (1992) Health Measurement Scales: A practical guide to their development and use. Oxford Medical Publications. Pgs 79-125.

Sunshine W, Field T, Quintino O, Fierro K, Kuhn C, Burman I and Schanberg S (1996) Fibromyalgia benefits from massage therapy and transcutaneous electrical stimulation. Journal of Clinical Rheumatology February 2 (1) 18-22.

Swayne J (1989) Survey of the use of homeopathic medicine in the UK health system. Journal of the Royal College of General Practitioners 39, 503-506.

Swinnerton T (1990) An alternative approach. Nursing Times 86 (36) 66-67.

Tate S (1997) Peppermint oil: a treatment for post-operative nausea. Journal Advanced Nursing Sept. 26 (3) 543-549.

Tattam A (1992) The Gentle Touch. Nursing Times 88 (32) 16-17.

Taylor P (1983) Massage in a special care nursery. The Australian Nurses Journal 12 (7) February 42-45.

The Canadian Cooperative Study Group (1978) The Canadian trial of aspirin and sulfinpyrazone in threatened stroke. New England Journal of Medicine 299, 53-59.

The Foundation for Integrated Medicine (1997): Integrated Healthcare. A way forward for the next five years? A discussion document.

The Royal College of Physicians (August 1996) Guidelines on the Practice of ethics committees in Medical Research involving human subjects. Third ed. The Royal College of Physicians, London.

Thomas KJ, Carr J, Westlake L and Williams BT (1991) Use of non-orthodox and conventional health care in Great Britain. British Medical Journal 302, 207-210.

Thomas KJ and Fitter MJ (1997) Evaluating complementary therapies for use in the National Health Service: 'Horses for courses'. Part 2: Alternative research stategies. Complementary Therapies in Medicine 5, 94-98.

Tiran D (1995) Massage and Aromatherapy. In Tiran D, Mack S (Eds) Complementary Therapies in Pregnancy and Childbirth. London, Bailliere Tindall.

Tiran D (1996) Aromatherapy in Midwifery Practice. Bailliere Tindall, London.

Tisserand R (1994) Aromatherapy today. Aroma 93 Conference Proceedings. Aromatherapy Publications, Brighton, pgs 2-4.

Trevelyan J (1993) Massage. Nursing Times 89 (19) 44-47.

Trevelyan J and Booth B (1993) Fringe Benefits. Nursing Times 89 (17) 30-33.

Trevelyan J (1996) A true complement. Nursing Times 92 ( ) 5.

Turton P (1989) Touch me, feel me, heal me. Nursing Times 85 (19) 42-44.

Tyler DO, Winslow EH, Clark AP and White KM (1990) Effects of a one minute back rub on mixed venous oxygen saturation and heart rate in critically ill patients. Heart Lung 19 (5) 562-565.

Tyler DC, Douthit AJ, Chapman CR (1993) Toward validation of pain measurement tools for children: a pilot study. Pain 52, 301-309.

United Kingdom Central Council for Nursing, Midwifery and Health Visiting (1992): Standards for the administration of medicine. UKCC, London.

United Kingdom Central Council for Nursing, Midwifery and Health Visiting (1992): The Scope of Professional Practice. UKCC, London.

Valdez RB, Ware JE, Manning WG, Brook RH, Rogers WH, Goldberg GA and Newhouse JP (1989) Prepaid group practice effects on the utilisation of medical services and health outcomes for children: Results from a controlled trial. Paediatrics 83, 168-180.

Vickers A and Rees R (1995) Information technology and complementary medicine research. Complementary Therapies in Nursing and Midwifery 1, 175-177.

Vickers A (1997) Yes, but how do we know its true? Knowledge claims in massage and aromatherapy. Complementary Therapies in Nursing and Midwifery 3, 63-65.

Vincent CA and Richardson PH (1987) Acupuncture for some common disorders: a review of evaluative research. Journal of the Royal College of General Practitioners 37, 77-81.

Vincent C and Furnham A (1997). The perceived efficacy of complementary and orthodox medicine: a replication. Complementary Therapies in Medicine 5, 85-89.

Visser J (1991) Alternative medicine in the Netherlands. In: Lewith G and Aldridge D (eds) Complementary Medicine and the European Community. Saffron Walden: CW Daniel.

Wafer M (1994) Finding the formula to enhance care: Guidelines for the use of complementary therapies in nursing practice. Professional Nurse 9 (41) 416-417.

Waldman C, Tseng P, Mevlman P and Whittet H (1993) Aromatherapy in the Intensive Care Unit. Care of the Critically ill 9 (4) July/August 170-174.

Wall PD (1996) The placebo effect. In The science of consciousness. Psychological, Neuropsychological and Clinical Reviews (Velmans M ed.) Routledge, London.

Wallston KA et al (1978) Development of the multidimensional health locus of control (MHLC) scales. Health Education Monographs 6, 161-170.

Walsh D (1996) Using aromatherapy in the management of psoriasis. Nursing Standard 11 (13) 11th-18th December), 53-56.

Walsh D and Morrissey M (1998) Aromatherapy: an approach to managing symptoms of stress. Mental Health Nursing 18 (5) 23-27.

Walsh E and Wilson C (1999) Complementary therapies in long stay neurology settings. Nursing Standard 13 (32) April 28th -May 4th, 32-35.

Ware JE, Brook RH, Rogers WH, Keller EB, Davies AR, Sherbourne CD, Goldberg GA, Camp P and Newhouse JP (1986) Comparison of health outcomes at a health maintenance organisation with those of free-for-service care. Lancet 1, 1017-1022.

Ware JE and Sherbourne CD (1992) The MOS 36-item short form health survey (SF-36).1.Conceptual framework and item selection. Medical Care 30, 473-481.

Watson S (1997) The effects of massage: an holistic approach. Nursing Standard 11 (47) 45-47.

Watts M (1992) Plant Aromatics Reference Manual. Published by Martin Watts, Essex.

Webster R and Thompson D (1986) Sleep in Hospital. Journal of Advanced Nursing 11, 447-457.

Weinrich SP, Haddock S, Robinson K (1999) Adult/elderly care nursing. Therapeutic massage in older persons: research issues. British Journal of Nursing 8 (3) February 11-24.

Weinrich SP and Weinrich MC (1990) The Effect of Massage on Pain in Cancer Patients. Applied Nursing Research 3 (4) 140-145.

Westwood C (1986) Aromatherapy. Health Visitor 59, August, 251.

Wharton R and Lewith G (1986) Complementary medicine and the general practitioner. British Medical Journal 292, 7th June, 1498-1500.

Which (1986) Magic or medicine. Which, October, 443-447.

White AR, Resch KL and Ernst E (1997) Complementary medicine: use and attitudes among General Practitioners. Family Practitioner 14 (4) 302-306.

White-Traut RC and Goldman MBC (1988) Premature infant massage: is it safe? Pediatric Nursing 14 (4) July-August 285-289.

WHO (World Health Organisation) (1983) Discussion document, September, 33rd session, Madrid.

Wiegant FAC, Kramers CW and van Wijk R (1991) Clinical research in complementary medicine: the importance of patient selection. Complementary Medical Research 5 (2) 110-115.

Wilkinson M (1991) The healing touch in an age of technology. Aromatherapy Quarterly 31, Winter, 3-4.

Wilkinson S (1995) Aromatherapy and massage in palliative care. International Journal of Palliative Nursing 1 (1) 21-30.

Wilkinson S, Aldridge J, Salmon I, Cain E and Wilson B (1999) An evaluation of aromatherapy massage in palliative care. Palliative Medicine 13, 409-417.

Williams A (1991) Essential oils in Nursing Project. November. Institute of Nursing, Oxford.
Wise R (1989) Flower power. Nursing Times 85 (22) 31st May, 45-47.

Wong M (1998) Treating High Blood Pressure and Arthritis with Aromatherapy. Aromatherapy Quarterly 58, Autumn, 27.

Woolfson A (1992) UK Hospital Report: aromatherapy in intensive care. Aromatherapy Quarterly 33, Summer, 25.

Woolfson A and Hewitt D (1992) Intensive Aromacare. The International Journal of Aromatherapy 4 (2) Summer, 12-13.

Wright SG (1989) The nurse as helper and healer. Nursing Standard 3 (25) 30-32.

Wright SG (1995) The competence to touch: helping and healing in nursing practice. Complementary Therapies in Medicine 3, 49-52.

Yasui Y and Hirone T (1994) Action spectrum for bergamot oil phototoxicity measured by sunburn cell counting. Journal of Dermatology 21 (5) May 319-322.

Zaynon S (1977) Contact Dermatitis 3, 225.

Zigmond AS and Snaith RP (1983) The hospital anxiety and depression scale. Acta Psychiatrica Scandinavica 67, 361-370.

Zinovieff K (1999) The need for quality in essential oils. Positive Health 38, March, 22-26.

Appendix 1

Patient and Relative Information Sheet

At the present time there is a study being undertaken on this intensive care unit to evaluate the use of massage and aromatherapy for patients in this unit. Aromatherapy is the use of massage using essential oils to promote health and serenity of mind.

The purpose of this study is to evaluate the use of bergamot oil and its reputed effects of being relaxing and an anti-depressant. The study involves patients being divided into three different groups:-

1) no massage or aromatherapy

2) massage for 30 minutes once every three days of their stay in intensive care

3) massage with bergamot oil for 30 minutes once every three days during their stay in intensive care

All groups of patients that take part in the study will continue to receive the highest possible care.

You or your relative would therefore be involved in **one** of these 3 groups. The study also involves an interview with you or your relative on admission to the intensive care unit, on discharge from the intensive care unit and one month after discharge from intensive care.

Nurses will be filling in charts relevant to the study during you or your relatives stay. All other patient care and treatment will continue as usual for you and your relative.

All information collected will be confidential.

If there are any questions which may arise during the study or if you require further information, you can contact;

NICKY OLLEVEANT (sister on ITU and research co-ordinator)

PAM SHEPARD (enrolled nurse on ITU and specialist in massage and aromatherapy)

I envisage no problems or risks occurring during these treatments, but as patients are continuously monitored in intensive care, very close observation and monitoring of the effects of each treatment will take place.

Royal Liverpool University·Hospital

PRESCOT STREET LIVERPOOL L7 8XP TEL: 051-706 2000 FAX: 051-706 5806

Appendix 2
Consent Form

Intensive Therapy Unit
Royal Liverpool University Hospital

WRITTEN INFORMED CONSENT FORM

THE EFFECTS OF AROMATHERAPY AND MASSAGE ON THE SENSORY PERCEPTIONS OF INTENSIVE CARE PATIENTS AND THEIR LONG TERM QUALITY OF LIFE.

Consent by patient (or patients representative) agreeing to participate in this study.

NAME OF PATIENT

The above mentioned study has been fully explained to me in detail and I have read and understood the information sheet. I fully understand the possible consequences and benefits to me (or my relative).

I .... (Name of consenting person)

hereby consent to participate/ to allow my relative to participate in this study on the understanding that I shall be entitled to withdraw this consent at any time, and that all information will remain confidential.

Signed ....
Please state if patient or your relationship to patient.

Date ....

I confirm that I have explained to the patient (or the patients representative) the purpose and nature of this study.

Signed ....

Date ....

Appendix 3

MASSAGE MOVEMENTS

1.	Effleurage whole leg	x12 (1 min 10 secs)
2.	Petrissage circles in ankle hollows and around joint	x10 (26 secs)
3.	Holding heel, rotate ankle clockwise and anticlockwise	x6 each way (13secs)
4.	Rotate each toe, as above	x6 each way (56secs)
5.	Pull toes, gently	once (11 secs)
6.	Effleurage foot, supporting heel	x20 (41 secs)
7.	Spread metatarsals	x2 (34 secs)
8.	Use flat of fist to stroke sole of foot	x6 (18 secs)
9.	Thumb slide on sole of foot	x2 (24 secs)
10.	Petrissage across top of foot	x3 (17 secs)
11.	Alternate stroking up front of leg	once (19 secs)
12.	Effleurage sides of leg, lift muscles, bring hands flat down front of leg	x2 (14 secs)
13.	Effleurage underneath leg, lift muscles, bring hands flat down front of leg	x2 (15 secs)
14.	Circle sides of leg	once (17 secs)
15.	Effleurage whole leg	x12 (1 min 17 secs)

Procedure to take 20 minutes, including changing of legs and re-application of oil.

Appendix 4.

Skin Patch Test for Sensitivity to Bergamot Oil

Patients who were randomly allocated to either experimental group 1 or experimental group 2 were required to have a skin patch test to determine any sensitivity to bergamot oil. Following randomisation into either of these two groups patients had a small amount of 2.5% bergamot oil applied in a small patch of 3sqcm to one of their thighs. The patch was then covered with a small piece of gauze to prevent anyone washing off the oil and left for 24 hours. After 24 hours the gauze was removed and the area was assessed for any evidence of sensitivity to the oil. Signs of any sensitivity included redness, swelling, itchiness, rash. If patients had any signs of sensitivity to the oil then they were removed from the trial and the reason why was explained to the patient and their relatives.

Appendix 5

The New Sheffield Sedation Scale (Laing 1992)

The nurse/doctor should assess the sedation of the patient hourly and their evaluations should be charted on the observation chart.

(1) Awake Level. At this level patients should be awake and orientated, requiring minimal or no sedation. They should also be self ventilating, either via a face mask or through an ET tube which they are tolerating. This level should be reached by the patient prior to being extubated after having gone through the weaning process successfully. This level with no sedation, is what may be aimed for in many patients who are ventilated, and have either a tracheostomy or a particular neurological problem.

(2) Agitation. At this level the patient is showing signs of agitation, restlessness, compromising ventilation, oxygenation and general condition. Observe for signs of distress on physiotherapy, suctioning of the ET tube and oropharynx, and on handling in general.

(3) Optimum level (i). This level of sedation should be were the patient is *'just asleep'. The patient should respond to speech and to touch either by squeezing of the nurses hand or by blinking. The patient may require bolus sedation as well as background sedation cover prior to handling during cares and also prior to physiotherapy sessions or any invasive procedures.

(4) Optimum level (ii). This level of sedation should be where the patients is *'just asleep'. The patient should respond to speech and to touch either by the squeezing of the nurses hand or by blinking. The patient should also handle well and tolerate care.

(5) Sluggish level. This level is where the patient has dull/sluggish responses to any form of stimulation ie glabellar tap or on suction through an ET tube.

(6) Flat level. This level is when the patient is showing no signs of response to stimulation of any kind.

* This is a level of sedation which allows patients to tolerate treatments and general nursing care, physiotherapy and suction without compromising their ventilation or cardiovascular state.

Sedation levels 5 and 6 are only acceptable in certain cases;

a) The patient who is receiving neuromuscular blockers. Heavy sedation is required for the comfort of the patient; the aim being to avoid the situation where a patient is being chemically paralysed, but not receiving adequate analgesia and sedation.

b) The extremely ill and unstable patient, where heavy sedation is required to manage his/her critical condition.

Please insert P when a patient is paralysed
S when a patient is sleeping

Appendix 6.

Pain Scale

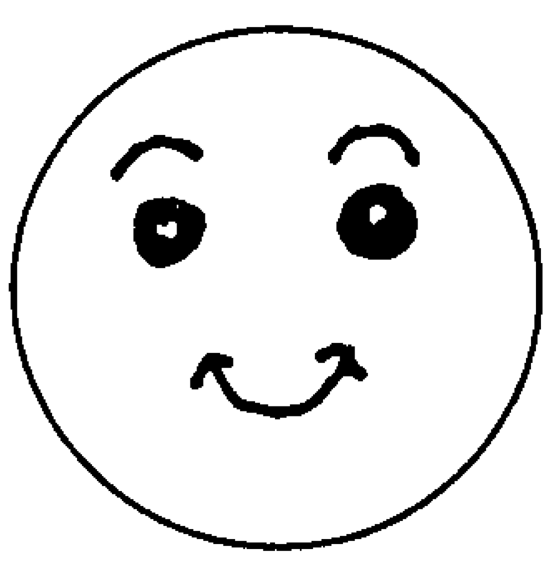
The nurse should assess the pain level of the patient hourly and their evaluations should be charted on the observation chart. This score should be recorded in the box which specifies sedation score. A line is to be drawn to divide the box in two ie / and the sedation score should be written on the top and the pain score on the bottom. The nurse or patient (if able) should assess for pain. If the patient is awake enough to use the faces scale, then this should be shown to the patient, and a score obtained. If the patient is unable to do this then the nurse must make this assessment.

Nurses assessment

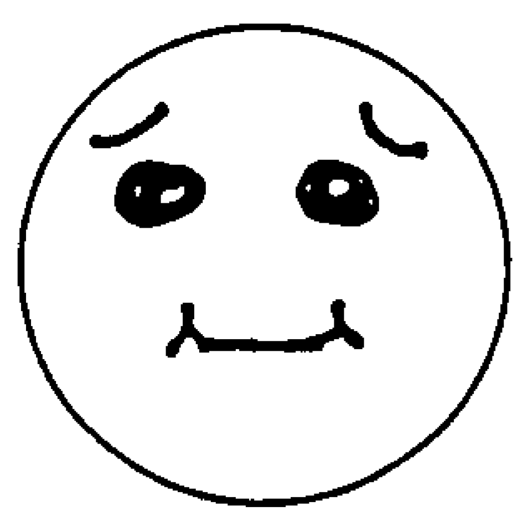
Unable to assess due to sleeping or paralysis	Insert S when a patient is sleeping Insert P when a patient is paralysed
Appears pain free	Insert PF
Appears in pain ie grimaces when moving	Insert AP

Patients assessment

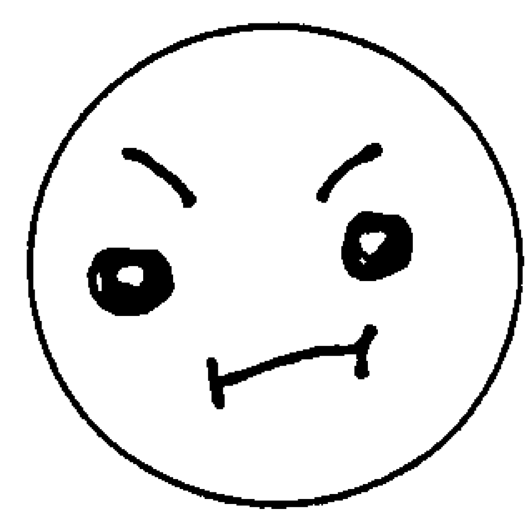
Use the faces below to show the patients so that they can assess their own pain when possible.
Use the letters in the brackets to score the patients pain.



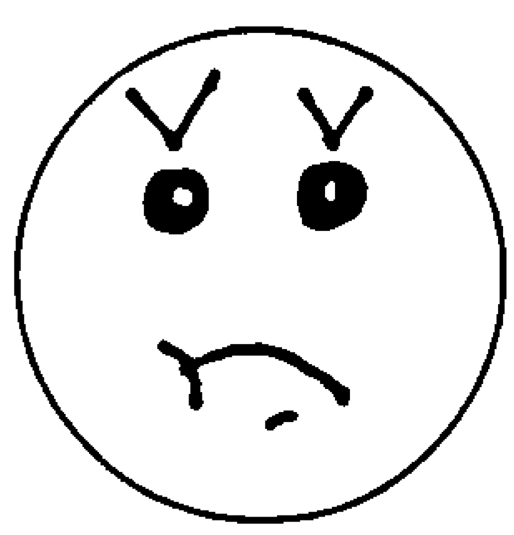
NONE (N)



MILD (MI)

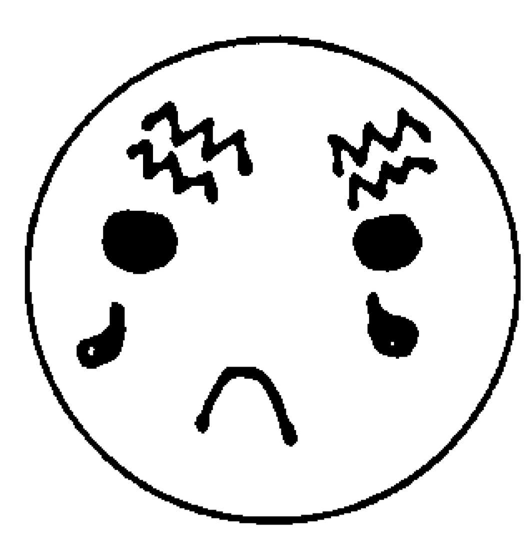


MODERATE (MO)



SEVERE (V)

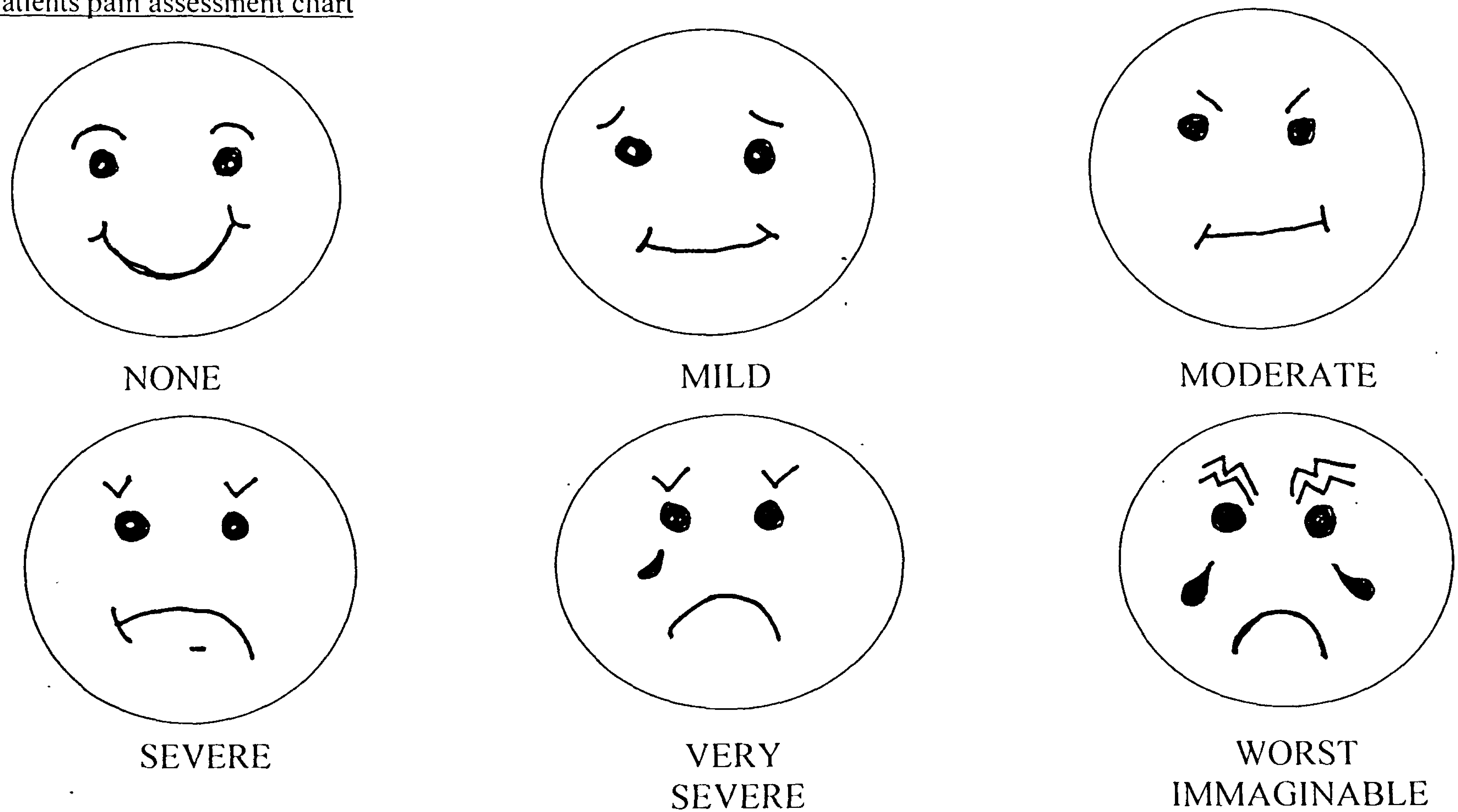
VERY SEVERE (VV)



WORST IMMAGINABLE (WI)

Appendix 6 (continued)

Patients pain assessment chart



Appendix 7.

Pilot Study.

A pilot study was undertaken during December 1993 to January 1994, in order to test the methods for data collection, and the organisation of the study. A number of objectives were set for the pilot study.

Objectives of Pilot Study.

1. To gain ethical approval for the study.
2. To obtain access to the study population, study nurses and the Intensive Care Unit (ICU).
3. To test the reliability of the instruments for data collection.
4. To test the validity of the instruments for data collection.
5. To make any necessary changes to the data collection schedules prior to commencement of the main study.
6. To train a core group of six nurses in the massage procedure and technique required for the study.

Sample.

Access to the ICU was gained prior to commencement of the pilot study from the Clinical Director and the Directorate manager of the ICU. The potential population comprised of all patients in the intensive care unit at a large teaching hospital in Liverpool, during the period of December 1993 to January 1994. The sample recruited into the pilot study comprised of 12 patients which consisted of all admissions to the intensive care unit who fulfilled the inclusion criteria for the study, and did not have any of the exclusion criteria.

Inclusion Criteria.
All patients admitted to the I.T.U. during the study period will be included in the trial.

Exclusion Criteria.

1. Patients who have a positive skin patch test. This involves a few drops of 2.5% Bergamot oil being applied to a small area of skin, and observing for any allergic reaction. If any redness or irritation occurs, then this would indicate a positive skin patch test.
2. Patients who are brain dead on admission and therefore fulfil brain death criteria.
3. Patients who are admitted for an overnight stay, or whose stay is less than 3 days.
4. Patients who do not wish to take part in the study, or whose relatives do not consent on behalf of the patient.
5. Patients who have any psychological aversions to being touched or handled.
6. Patients who have any contagious or infectious skin conditions.

Method

Consent was obtained to take part in the pilot study and patients were randomly allocated to one of three groups which resulted in four patients in each group

Control group	4 patients
Experimental group 1	4 patients
Experimental group 2	4 patients

Results

No problems were encountered during the pilot study regarding consent and patient recruitment. All patients and relatives invited to participate, agreed to take part in the study.

Methods for Data Collection.

On entering the study, detailed demographic data was recorded including age, sex, social class, medical diagnosis, APACHE 11, which is a severity of disease scale (Knaus et al 1985), and a list of life events (Holmes and Rahe 1963) which had occurred to that patient over the past year. The demographic data and the list of life events were taken from the patient if able, or from the next of kin.

Quantitative and qualitative were both collected for the study.

Quantitative Data.

Many instruments were used to collect this data. The TISS (therapeutic intervention scoring system, Cullen et al 1983), was used to measure the activity per day for each patient, so that any differences between patients daily activity could be captured. A six point pain scale was used to assess the patients pain and a similar scale, the Sheffield sedation scale was used to assess the patients sedation level. Physiological recordings of blood pressure, heart rate and respiratory rate were also recorded. These measurements will be used to supplement the information collected on patients experiences of pain and anxiety (Boore 1976). The TISS was recorded daily as was the length of time relatives visited the patient.

Three structured questionnaires were also used, and these were the SF 36 (Ware et al 1993), used to measure the quality of life, the Hospital Anxiety and Depression Scale (Zigmond and Snaith 1983), used to measure anxiety and depression, and the General Health Questionnaire 12 (Goldberg 1972), used to measure depression. These were administered on discharge from I.T.U., and again one month later. The questionnaires were given to the patients to complete, and then checked that all sections were completed. At one months time the questionnaires were administered by post, as all patients except one had been discharged home. The patient which remained in hospital was given the questionnaire to complete.

Qualitative Data.

A 4th short semi-structured questionnaire was developed to ask patients about their experiences in I.T.U. (both pleasant and unpleasant), to determine if any similar experiences were occurring and to determine if they remembered the study intervention or not. This was administered with the other questionnaires, at discharge from I.T.U., and one month later, by the same method as the first set of questionnaires.

The Intervention.
The intervention began the day after the patients admission to I.T.U. If the patient was in experimental group 2, then a skin patch test was performed to test for sensitivity to Bergamot oil 2.5%. This involved a few drops of 2.5% Bergamot oil being applied to a small area of skin on the leg, and observing for any signs of sensitivity after 24 hours. Experimental group 1 and 2 each then received the appropriate intervention lasting for 20 minutes, every 3rd day of their stay on I.T.U. Both legs were massaged as part of the intervention, according to a standard protocol (see table 1). Physiological recordings as well as pain and sedation scores were recorded pre and post intervention, 1 hour post intervention and 4 hours post intervention.

Ethical Approval.
Ethical approval was sought during March 1993, from the Chairman of the ethics committee at the Royal Liverpool University Trust Hospital, and was gained in June 1993, after an amendment to the patient and relative information sheet.

There were many ethical points to consider to undertake this research in I.T.U., the primary one being that patients are often too ill to consent to be in a study and therefore the relatives have to consent on behalf of them.
Informed consent.

Informed consent is difficult to obtain from patients in I.T.U., as they usually present to I.T.U., with no prior knowledge of their admission, and their illness is usually so severe that they are sedated and ventilated and therefore are not in a position to consent to take part in a research study. In these cases the next of kin is asked to consent on behalf of the patient, and this in itself can add stress to the relatives who are already feeling venerable. The patient if able, or the next of kin, receive an explanation about the study, together with an information sheet including contact names and numbers if needed, so that they are able to make an informed decision about entering the study.

Anonymity and Confidentiality.
To maintain anonymity, only patient initials were used and each patient was assigned a code number for use in the study. This code was used throughout the study so that questionnaires would match patient data.

Patients and their next of kin, were also told that any information collected would be confidential.

The right to refuse and withdraw from participation.
Patients and their next of kin were given the right to refuse participation, in the study and advised that they also had the choice to withdraw from participation at any point during the study.

Protection from harm.
It is envisaged that there will be no adverse effects from using massage and/or Bergamot oil 2.5%. No adverse effects were noted in the pilot study. A record will be kept of any adverse problems related to this study, and all recorded problems associated with using Bergamot oil have been taken into account i.e. the effects of

photosensitivity when exposed to sunlight of some types of Bergamot oil. The Bergamot oil used in this study is not thought to cause problems with photosensitivity when exposed to sunlight. A skin patch test is performed on each patient entering experimental group 2, to assess for sensitivity to Bergamot oil 2.5%.

Reliability and Validity.
Reliability.
Reliability testing was performed on the following items:-

sedation scale
pain scale
massage timing
massage technique

See preliminary results from pilot study.
Validity.

Revision of Data Collection Schedule.

On the basis of the pilot study, the following revisions were made for the main study:-

1. Patients as well as the next of kin were asked to complete a list of life events about the patient. If the patient was unable to complete this list on admission they were asked to complete it when they are able.
2. The GHQ 12 was excluded from use in the main study due to patients finding the number of questionnaires for completion overwhelming and some patients not completing all the questionnaires. A further factor which contributed to this decision was that the GHQ 12, recorded higher scores demonstrating a ceiling effect, and it appeared that the HAD was more sensitive for this group of patients. The GHQ 12 was designed for use in the community and this may be one of its problems in this study whereas the HAD was designed for use in an hospital setting. The SF36 also addresses depression in its questions and it was therefore felt that the HAD and the SF36 would be adequate when used together, for measuring depression.
3. Patients were excluded from the study if they were discharged from ICU for 48 hours or longer, and then readmitted.
4. The first set of questionnaires were to be completed on the intensive care unit before the patient was discharged.
5. If the second set of questionnaires, which were administered one month after completion of the first set of questionnaires were posted to the patient (either to the hospital ward or to their home address) and were not returned within two weeks, then the patient was followed up with a telephone call to ensure that the patient had received the questionnaires, and to emphasise the importance of the patient completing them. It was envisaged that this would improve compliance.

Data Management and Analysis.

All coded data will be entered onto computer and analysed using SPSS PC. The data will undergo factorial analysis of variance to compare the 3 groups and any further subgroups which emerge. Differences between the groups will be identified using multiple regression.

Preliminary Results from Pilot Study.

The data collection schedules were tested during the pilot study, and a few amendments have been made for the main study.

A total of 12 patients were admitted into the pilot study, resulting in 4 patients in each study group:-

Control	4 patients (2 male, 2 female)
Massage only	4 patients (1 male, 3 female)
Massage and aromatherapy	4 patients (1 male, 3 female)

The mean age of all patients admitted into the study was 57. The types of illnesses the patients in the study group appeared to be fairly typical of the usual patients admitted to this I.T.U. They consisted of 8 acute surgical patients, 2 acute medical patients, and 2 chronic medical patients.

All patients who survived the pilot study were able to complete the questionnaires, but not all the patients completed both sets of questionnaires. 4 of the 7 patients who survived completed both sets of questionnaires, one of the patients remained too confused to complete the second set of questionnaires one month after discharge from I.T.U. The table below indicates some preliminary data from the pilot study using the SF36, indicating little change in the quality of life one month after discharge from I.T.U. This set of data is too small to generalise and therefore the larger data set gained from the main study will give more valuable data regarding this.

SF 36	Post discharge	One month post discharge
Physical function	58.75	35
Role limitation (physical)	43.75	12.5
Role limitation (mental)	58.33	56.25
Social function	61.10	61.10
Mental health	67	64
Energy/Vitality	55	46.25
Pain	66.65	80.55
General health perceptions	64	53.5
Change in health	31.25	50

(n = 4) Note: higher values = an increased quality of life.

Reliability testing of Instruments.

Pain Scale.

Inter observer checks were performed, and the Kappa coefficient calculated. K = 1.00 (n = 6). This indicates an excellent reliability test, but it has only been performed on a small sample of subjects and further reliability testing throughout the study is necessary.

Sedation Scale.
Inter observer reliability checks were performed, and the Kappa coefficient calculated. K = 0.89 (n = 10). This also indicates an excellent reliability, but again more inter rater observers are required, and reliability checks will be continued throughout the study.

Massage Technique.
Inter observer reliability checks were performed and the Kappa coefficient calculated. K = 1.00 (n = 6) The massage technique was strictly adhered to, and therapists have a list of the massage protocol with them whilst massaging, and this was followed at all times.

Massage Timing.
Inter observer reliability checks were performed, and the Pearsons correlation coefficient calculated. A good reliability was achieved with the massage timings as shown below:-

Masseur	Instruction time (r)
1	$r = 0.974$
2	$r = 0.982$
3	$r = 0.981$
4	$r = 0.983$
5	$r = 0.985$
6	$r = 0.982$

$P < 0.001$

Some of the comments received during the pilot study, also suggested that patients require interventions to help them to relax and sleep. 71.4% of patients said that they could remember their stay in I.T.U., and 57.1% of patients in the study said that they felt afraid, anxious, worried or that they could not sleep. The main study is hoped to show that massage and aromatherapy will make patients stay in I.T.U. less anxiety provoking and more restful.

DISCERE SIMUL ET SANARE

Royal Liverpool University·Hospital

FIAT LUX

PRESCOT STREET LIVERPOOL L7 8XP TEL: 051-706 2000 FAX: 051-706 5806

Your Ref: Appendix 8
Ethical Approval

Our Ref: MC/ARM/93/40

If telephoning please ask for: 3158

Please quote our reference

18th June 1993

Miss N. A. Olleveant,
Sister on Intensive Care,
Intensive Care Unit,
Royal Liverpool University Hospital.

Dear Miss Olleveant,

THE EFFECTS OF AROMATHERAPY AND MASSAGE ON THE SENSORY PERCEPTIONS OF INTENSIVE CARE PATIENTS AND THEIR LONG TERM QUALITY OF LIFE.

Thank you for your letter of 15th June 1993 addressed to Dr. Bell (away from the office this week), and for amended patient/relative information sheet you enclosed. The Ethics Committee formally approves the abovementioned protocol.

Yours sincerely,

Dr. M. Critchley,
Deputy Chairman,
Ethics Committee.

Appendix 9

Weighting Discussion

Various methods of weighting the data were considered to take account of the total number of massages patients received during their stay in ICU, as this may have exerted some effect on those patients who received more than one massage assuming that the effects of massage are related to the number received. The number of massages received ranged from none to six.

The first ideas to deal with the data was by splitting it into two groups, those patients who received two or less massages and those patients who received three or more massages as another method of weighting the data. However the majority of patients received one or two massages (n=105 70%) which meant that to split the data in this way would only leave five cases in the more than three massage group, ie two patients in the massage only group and three patients in the aromatherapy massage group which had responded to both sets of questionnaires.

Another idea was to weight the data using MANOVA but this was not suitable as it was impossible unable to weight the data when undertaking repeated measures as the computer package could not undertake this.

Thirdly linear regression (conditional) was considered, but this only examines those groups who received the intervention and not the control group. By artificially giving the control group massage numbers the whole analysis is affected. However the patient numbers would also have been too small to do this.

A fourth and final consideration was that if the massage only group and aromatherapy massage group were similar enough then they could have been collapsed together and compared against the control group.

After considering all of the points above it was decided that weighting the sample sizes available would be invalid and would not add any further information to the analysis.