Keywords

Aromatherapy, Beliefs, Complementary therapy, Evidence based practice, Nursing care, Postoperative nausea and vomiting, Postoperative care, Systematic review.
Abstract

Background: Postoperative nausea and vomiting is one of the most common adverse reactions to surgery and all types of anaesthesia and despite the wide variety of available antiemetic and anti-nausea treatments, 20-30% of all patients still suffer moderate to severe nausea and vomiting following general anaesthesia. While aromatherapy is well-known and is used personally by nurses, it is less well utilised in the healthcare setting. If aromatherapy is to become an accepted adjunct treatment for postoperative nausea and vomiting, it is imperative that there is both an evidence base to support the use of aromatherapy, and a nursing workforce prepared to utilise it.

Methods: This involved a Cochrane Systematic Review, a Delphi process to modify an existing tool to assess beliefs about aromatherapy to make it more relevant to nursing and midwifery practice, and a survey to test the modified tool in a population of nurses and midwives.

Findings: The systematic review found that aromatherapy with isopropyl alcohol was more effective than placebo for reducing the number of doses of rescue antiemetics required but not more effective than standard antiemetic drugs. The Delphi panel process showed that the original Beliefs About Aromatherapy Scale was not completely relevant to nursing and midwifery practice. The modified Nurses’ Beliefs About Aromatherapy Scale was found to be valid and reliable to measure nurses’ and midwives’ beliefs about aromatherapy. Factor analysis supported the construct validity of the scale by finding two sub-scales measuring beliefs about the ‘usefulness of aromatherapy’ and the ‘scientific basis of aromatherapy’. Survey respondents were found to have generally positive beliefs about aromatherapy, with more strongly positive beliefs on the ‘usefulness of aromatherapy’ sub-scale.

Conclusions: From the evidence of the systematic review, the use of isopropyl alcohol vapour inhalation as an adjunct therapy for postoperative nausea and vomiting is unlikely to be harmful and may reduce nausea for some adult patients. It may provide a useful therapeutic option, particularly when the alternative is no treatment at all.

Given the moderately positive beliefs expressed by nurses and midwives particularly about the usefulness of aromatherapy there is potential for this therapy to be implemented and used to improve patient care.
**Table of Contents**

Keywords ........................................................................................................................................... ii

Abstract ............................................................................................................................................... iii

Table of Contents ........................................................................................................................ iv

List of Figures ..................................................................................................................................... x

List of Tables ...................................................................................................................................... xi

List of Abbreviations ..................................................................................................................... xii

Publications Arising from this Work .......................................................................................... xiii

Statement of Original Authorship ............................................................................................... xiv

Acknowledgements ........................................................................................................................... xv

**CHAPTER 1: INTRODUCTION** .................................................................................................. 1

1.1 BACKGROUND ........................................................................................................................... 1

1.1.1 Postoperative Nausea and Vomiting .................................................................................. 1

1.1.2 Current Treatment for Postoperative Nausea and Vomiting ........................................... 1

1.1.3 Aromatherapy .................................................................................................................. 2

1.1.4 Aromatherapy for Postoperative Nausea and Vomiting .................................................... 3

1.2 Context ......................................................................................................................................... 4

1.3 Purposes ....................................................................................................................................... 4

1.3.1 Aims and Objectives ......................................................................................................... 4

1.3.2 Research Questions ........................................................................................................... 5

1.4 Significance, Scope and Definitions ......................................................................................... 5

1.4.1 Significance ...................................................................................................................... 5

1.4.2 Scope ................................................................................................................................ 5

1.4.3 Definitions ........................................................................................................................ 6

1.5 Thesis Outline ............................................................................................................................ 7

**CHAPTER 2: LITERATURE REVIEW** ..................................................................................... 9

2.1 Risk Factors for Postoperative Nausea and Vomiting .............................................................. 9
CHAPTER 4: SYSTEMATIC REVIEW ........................................................................ 43

4.1 Background ........................................................................................................ 43
  4.1.1 Aromatherapy and Postoperative Nausea and Vomiting ............................. 43
  4.1.2 Cochrane Review Methodology ................................................................ 46

4.2 Objectives ........................................................................................................... 47

4.3 Methods ............................................................................................................. 48
  4.3.1 Criteria for Considering Studies for This Review ..................................... 48

4.4 Search Methods for Identification of Studies .................................................... 49
  4.4.1 Electronic Searches .................................................................................... 49
  4.4.2 Searching Other Resources ....................................................................... 49

4.5 Data Collection and Analysis .......................................................................... 50
  4.5.1 Selection of Studies .................................................................................... 50
  4.5.2 Data Extraction and Management ............................................................... 50
  4.5.3 Assessment of Risk of Bias in Included Studies ........................................ 50
  4.5.4 Measures of Treatment Effect .................................................................. 50
  4.5.5 Unit of Analysis Issues .............................................................................. 51
  4.5.6 Dealing with Missing Data ......................................................................... 51
  4.5.7 Assessment of Heterogeneity .................................................................... 51
  4.5.8 Assessment of Reporting Biases ................................................................. 51
  4.5.9 Data Synthesis ............................................................................................ 51
  4.5.10 Subgroup Analysis and Investigation of Heterogeneity ......................... 52
  4.5.11 Sensitivity Analysis ................................................................................... 52

4.6 Results .............................................................................................................. 52
  4.6.1 Description of Studies .............................................................................. 52
  4.6.2 Results of the Search ................................................................................ 52
  4.6.3 Included Studies ....................................................................................... 54
  4.6.4 Excluded Studies ...................................................................................... 54
5.2.1 Sample Characteristics ................................................................. 76
5.2.2 Validity and Reliability of the N-BAAS ........................................ 78
5.2.3 Mean Levels of Belief about Aromatherapy .................................... 80
5.2.4 Relationships Among Demographic Variables and N-BAAS ............ 80
5.3 Summary ............................................................................................. 81

CHAPTER 6: DISCUSSION ........................................................................ 82
6.1 Effectiveness of Aromatherapy to Treat Postoperative Nausea and Vomiting .... 82
   6.1.1 Summary of Systematic Review Results ........................................ 82
   6.1.2 Levels of Evidence in the Systematic Review ................................. 84
   6.1.3 Adverse Effects Reported in Studies Included in the Systematic Review ... 84
   6.1.4 Agreement and Disagreement with Other Studies or Reviews .......... 85
   6.1.5 Complementary Therapies Research ............................................. 86
   6.1.6 Gaps in the Current Evidence Base ............................................... 87
6.2 Modification of the Beliefs about Aromatherapy Scale ....................... 88
   6.2.1 The Delphi Panel ........................................................................... 88
   6.2.2 Delphi Process ............................................................................ 89
   6.2.3 Additional Items .......................................................................... 90
   6.2.4 Deleted Items ............................................................................... 91
6.3 Testing of the Modified n-baas Tool .................................................. 92
   6.3.1 Psychometric Testing of the N-BAAS Tool .................................... 92
   6.3.2 Representativeness of the Sample ................................................. 93
   6.3.3 Factor Analysis for Determining Construct Validity ....................... 94
   6.3.4 Sub-scales .................................................................................. 95
   6.3.5 Future Modifications to the Scale ............................................... 96
   6.3.6 Nurses’ Beliefs About Aromatherapy ......................................... 97
6.4 Summary ............................................................................................. 98

CHAPTER 7: CONCLUSIONS ................................................................. 99
7.1 Conclusions ....................................................................................... 99
   7.1.1 Is aromatherapy an effective treatment for postoperative nausea and vomiting? .... 99
7.1.2 Can aromatherapy be used to treat postoperative nausea and vomiting with clinical safety comparable to that of pharmacological antiemetics? ......................... 99

7.1.3 Is the Beliefs About Aromatherapy Scale relevant to nursing and midwifery practice or does it require modification before use with a population of nurses? ...... 100

7.1.4 Is the modified Nurses’ Beliefs About Aromatherapy Scale valid and reliable? ............ 100

7.2 Limitations .......................................................................................................................... 100

7.2.1 Limitations of the Systematic Review ......................................................................... 100

7.2.2 Limitations of the Delphi Process ................................................................................ 102

7.2.3 Limitations of the Instrument and Survey ................................................................... 102

7.3 Implications for Clinical Practice ..................................................................................... 103

7.4 Implications for Research ................................................................................................. 105

BIBLIOGRAPHY 107

APPENDICES 125

Appendix A .............................................................................................................................. 125

Appendix B .............................................................................................................................. 126

Appendix C .............................................................................................................................. 128

Appendix D .............................................................................................................................. 131

Appendix E .............................................................................................................................. 132

Appendix F .............................................................................................................................. 134

Appendix G .............................................................................................................................. 136

Appendix H .............................................................................................................................. 138

Appendix I .............................................................................................................................. 139

Appendix J .............................................................................................................................. 141

Appendix K .............................................................................................................................. 143

Appendix L .............................................................................................................................. 144

Appendix M .............................................................................................................................. 146

Appendix N .............................................................................................................................. 168

Appendix O .............................................................................................................................. 171
List of Figures

<table>
<thead>
<tr>
<th>Figure 4.1 Searching Flowchart</th>
<th>49</th>
</tr>
</thead>
<tbody>
<tr>
<td>Figure 4.2 Methodological quality graph</td>
<td>50</td>
</tr>
<tr>
<td>Figure 4.3 Methodological quality summary</td>
<td>51</td>
</tr>
<tr>
<td>Figure 4.4 Analysis 1</td>
<td>56</td>
</tr>
<tr>
<td>Figure 4.5 Analysis 2</td>
<td>56</td>
</tr>
<tr>
<td>Figure 4.6 Analysis 3</td>
<td>57</td>
</tr>
<tr>
<td>Figure 4.7 Analysis 4</td>
<td>58</td>
</tr>
<tr>
<td>Figure 4.8 Analysis 5</td>
<td>60</td>
</tr>
</tbody>
</table>
List of Tables

4.1 Studies measuring time to relief of nausea ........................................ 54
4.2 Studies measuring a decrease in nausea scores ................................ 55
4.3 Summary of findings 1 ...................................................................... 56
4.4 Summary of findings 2 ...................................................................... 58
4.5 Patient satisfaction with treatment ................................................. 60
5.1 Relevance of N-BAAS items for three Delphi rounds ..................... 70
5.2 Comparison of items in original BAAS and modified N-BAAS ........ 71
5.3 Sample characteristics .................................................................... 73
5.4 Pattern matrix for factor analysis of N-BAAS ................................. 75
5.5 Differences between those more or less than 5 years’ experience .... 79
List of Abbreviations

PONV – Postoperative nausea and vomiting
PDNV – Post-discharge nausea and vomiting
BAAS – Beliefs About Aromatherapy Scale
N-BAAS – Nurses Beliefs About Aromatherapy Scale
VAS – Visual Analogue Scale
NRS – Numeric Rating Scale
IV – Intravenous
RR – Relative Risk
ARR – Absolute Risk Reduction
CI – Confidence Interval
OR – Odds Ratio
CRG – Cochrane Review Group
CARG – Cochrane Anaesthetic Review Group
EFA – Exploratory factor analysis
M – Mean
SD – Standard deviation
Publications Arising from this Work

Hines S, Chang A. “Modifying and testing a tool to measure nurses’ and midwives beliefs about aromatherapy.” (Accepted for oral presentation) The 8th Biennial Joanna Briggs Colloquium. Chiang Mai, Thailand.


Statement of Original Authorship

The work contained in this thesis has not been previously submitted to meet requirements for an award at this or any other higher education institution. To the best of my knowledge and belief, the thesis contains no material previously published or written by another person except where due reference is made.

Signature: __________________________

Date: __________________________
Acknowledgements

I would like to acknowledge the valuable help and support of my supervisor, Professor Anne Chang and my associate supervisor, Patsy Yates. I could not have done this without the support of my children, Amanda, Ben and Nic. Nic deserves special thanks for being the kitchen whizz. My friends, here and abroad, listened to my woes and sent cake when it was desperately needed. Thanks also to my colleagues at the Nursing Research Centre for all their support, and special thanks to Sue Wright for all her help with technical difficulties large and small.

Thank you all.
Chapter 1: Introduction

This chapter outlines the background (section 1.1) and context (section 1.2) of the research, and its purposes (section 1.3). Section 1.4 describes the significance and scope of this research and provides definitions of terms used. Finally, section 1.5 includes an outline of the remaining chapters of the thesis.

1.1 BACKGROUND

1.1.1 Postoperative Nausea and Vomiting

Postoperative nausea and vomiting (PONV) is a complex phenomenon and, for patients, one of the most unpleasant and distressing effects of surgery\(^1\). Nausea is an abdominal discomfort or queasiness that may be accompanied by vomiting (the forceful expulsion of stomach contents through the mouth)\(^2\). Certain patients are more pre-disposed than others to suffering from PONV and risk factors include: being female, a non-smoker, having a history of PONV, or peri-operative opioid exposure\(^1\). Along with postoperative pain, PONV is one of the main concerns of patients facing surgery and one of the main causes of patient dissatisfaction\(^3\).

As one of the most common adverse reactions to surgery and despite the wide variety of available antiemetic and anti-nausea treatments, PONV affects 20-30% of all patients following general anaesthesia\(^4\). Aside from the distressing nature of PONV itself, as a consequence of vomiting, patients may experience such adverse effects as wound dehiscence, dehydration, electrolyte imbalances, reduced nutrition, oesophageal rupture or aspiration pneumonia\(^5\). PONV is also associated with increased health care costs related to increased patient bed days, unplanned readmissions (particularly in the case of day surgery)\(^6\), decreased patient satisfaction\(^3\), and increased expenditure on antiemetic drugs\(^4\).

1.1.2 Current Treatment for Postoperative Nausea and Vomiting

Current treatment of PONV is either prophylactic or symptomatic involving the administration of antiemetic drugs such as droperidol, metoclopramide or 5-HT3 receptor antagonists such as ondansetron\(^7\). Despite a wide range of available treatments, some patients will still experience PONV in varying levels of severity\(^8\). One study of anaesthesiologists' prescribing patterns showed that 5-HT3-receptor antagonists were the initial treatment of choice (for postoperative
patients who had received no other antiemetic prophylaxis prior to surgery) for two-thirds of anaesthesiologists. Re-dosing with ondansetron was also found to be a common practice, despite evidence that indicates a second dose does not provide increased effect. These practices inevitably add to the cost of providing treatment for PONV, without clear patient benefit and with the attendant risks of increased adverse effects such as headache and constipation (ondansetron), drowsiness (promethazine) or dystonic or dyskinetic symptoms (metoclopramide).

1.1.3 Aromatherapy

Aromatherapy uses the application of essential oils or other scented substances to any part of the body for the purposes of inhalation of the vapours or absorption of the oil into the skin to treat or alleviate physical and emotional symptoms. It has also been defined as, “the use of pure essential oils from various parts of a plant, including the blossoms, roots, or leaves, to help improve physical and mental health, quality of life in general,”. For the purposes of this thesis, the former definition is used, as a broader, more pragmatic interpretation of the therapy is in use in healthcare.

Aromatherapy has been investigated for such conditions as nausea and vomiting, anxiety, dementia and pain. The aromatherapy literature also includes recommendations for use in palliative care, skin conditions, infective disorders, infertility and fatigue, but these claims are less well-supported.

It is difficult to trace the history of aromatherapy; some believe it to have originated between 4500-6000 years ago in Europe, Asia and/or the Middle East. Scented substances, mainly incense, made from aromatic plants were certainly known and used in ancient civilisations. Frankincense and myrrh are probably the best known of these through their Biblical associations, but there were many others used. It seems likely that the modern practice of aromatherapy began in Europe, probably Germany, in the 16th century. The process of steam distilling essential oils from plants to use as medicine is a relatively recent one and most of the development of what we now know as aromatherapy occurred in the 20th century.

Aromatherapy is well accepted by many health consumers who find it more pleasant and acceptable than the ingestion or injection of conventional drugs. Recent increased interest in alternative and complementary therapies have brought some traditional therapies into renewed prominence. A significant
number of health consumers already self-prescribe and administer aromatherapy products for various common conditions or consult qualified or unqualified aromatherapy practitioners for health advice\(^3\).

Aromatherapy also has the potential to reduce healthcare costs. An aromatherapy treatment such as peppermint oil may cost as little as ten cents per dose (retail cost averaged across suppliers) and isopropyl alcohol (referred to in “aromatherapy” in health research literature\(^15, 17\)) as little as four cents per dose and have little or no known adverse effects in standard dosages\(^14\). Given the prevalence of PONV in surgical patients and the consequent expenditure on antiemetic drugs in standard medical treatment regimes, there are clearly considerable savings to be made if the safety and effectiveness of aromatherapy can be established.

### 1.1.4 Aromatherapy for Postoperative Nausea and Vomiting

Previous systematic reviews on non-pharmacologic management of PONV have focused on evaluating acupressure/acupuncture-type interventions\(^32\), or the use of orally administered ginger extract\(^33\). There are no published reviews of aromatherapy interventions for PONV, despite the growing interest in, and awareness of, aromatherapy both in healthcare and in the community at large\(^34\). If the effectiveness of aromatherapy can be established it may add a valuable, low-cost adjunct to the current treatments for PONV with applications for healthcare systems worldwide.

Aromatherapy is a new tool for clinicians managing PONV, with the research centred on ginger oil\(^33, 35-37\), isopropyl alcohol\(^15-19, 38-40\) and peppermint oil\(^14, 15, 41\). The use of aromatherapy oils is recognized as an effective treatment for nausea in general\(^11, 28\). Isopropyl alcohol, while not a traditional aromatherapy treatment and not an essential oil, is commonly listed in the research literature as aromatherapy when the vapours are used for this purpose\(^15, 18, 42\).

The adoption of aromatherapy in clinical practice is not high. One study of Australian nurses' use of complementary therapies found that aromatherapy was used\(^43\), but only 19.5% of participants had utilised this therapy in clinical practice. This study did not specify what kind of aromatherapy was used, or for which condition, and so no further extrapolations can be made from these findings. Notably, however, aromatherapy was the most popular complementary therapy for the nurses' personal use (41.1%), which suggests a moderately high level of acceptance of the value of this therapy. Wilkinson’s study does not report the reasons for the lower rate of professional use. Similar findings were
made in another Australian study\textsuperscript{44} which explored nurses’ use of many types of complementary therapies. It was found that participants were generally unclear on the definition of complementary therapies, but overall had a positive attitude to their use.

Studies from other countries reflect the same general trend. Nurses in the UK were found to have fair levels of knowledge about complementary therapies in general, but low intentions to use them in their clinical practice, for a variety of reasons, such as lack of evidence or lack of institutional support\textsuperscript{45}. Nurses in the US were similarly found to use complementary therapies for themselves more frequently than on their patients\textsuperscript{46}. Nurses in Taiwan also have been found to have generally positive attitudes to aromatherapy use in practice\textsuperscript{47}, though this study again found low levels of usage in practice. In all of these studies, aromatherapy ranked highly among the complementary therapies used.

\textbf{1.2 CONTEXT}

Despite the large range of pharmacological antiemetics available to clinicians, a significant proportion of patients undergoing anaesthesia in ambulatory and in-patient settings will still suffer PONV. While aromatherapy is well-known and is used personally by nurses, it is less well utilised in the professional setting. If aromatherapy is to become an accepted adjunct treatment for postoperative nausea and vomiting, it is imperative that there is both an evidence base to support the use of aromatherapy, and a nursing workforce who are prepared to utilise it.

\textbf{1.3 PURPOSES}

\textbf{1.3.1 Aims and Objectives}

The aims of this research were to evaluate and synthesise the current best evidence on aromatherapy for PONV and to prepare a tool to examine nurses’ beliefs about using aromatherapy to provide a basis for further study on the implementation of this therapy in practice. The first objective was the completion and publication of a Cochrane systematic review on the topic to synthesise evidence for clinicians in a widely available and highly regarded publication. The second objective was to modify and validate, using psychometric methods, an existing survey instrument to assess nurses’ beliefs about the use of aromatherapy in practice and fill a gap in the current body of research.
1.3.2 Research Questions

1. Is aromatherapy an effective treatment for postoperative nausea and vomiting?

2. Can aromatherapy be used to treat postoperative nausea and vomiting with clinical safety comparable to that of pharmacological antiemetics?

3. Is the Beliefs About Aromatherapy Scale\(^\text{48}\) relevant to nursing and midwifery practice or does it require modification before use with a population of nurses?

4. Is the modified Nurses’ Beliefs About Aromatherapy Scale valid and reliable?

1.4 SIGNIFICANCE, SCOPE AND DEFINITIONS

1.4.1 Significance

Aromatherapy is a widely used complementary therapy with an incomplete evidence-base\(^\text{49}\) and variations on aromatherapy like isopropyl alcohol are used to treat PONV in some settings\(^\text{50}\). Postoperative nausea and vomiting occurs in 30-80% of all surgical cases and is one of the chief causes of patient dissatisfaction with the surgical experience\(^\text{3}\). Even universal antiemetic prophylaxis with current antiemetic drugs does not prevent PONV in all patients; it is estimated that if 100 patients were given a preoperative antiemetic drug approximately 28 would benefit and 72 would not\(^\text{51}\).

Despite the clear need for a strong evidence base for treating PONV, there is currently no published systematic review on the use of aromatherapy to treat PONV\(^\text{52}\) with systematic reviews considered to be the “gold standard” in evidence for healthcare interventions\(^\text{53}\). Furthermore, if aromatherapy is effective for PONV, it is important to know what nursing staff believe about it, in order to facilitate its integration into practice. The modification and validation of an instrument to assess nurses’ beliefs about aromatherapy will provide researchers with a useful tool for assessing nursing staff beliefs in their own facilities.

1.4.2 Scope

Systematic Review: The scope of the systematic review is global. In order to present a full overview of the research evidence, all randomised controlled trials and controlled clinical trials that meet the inclusion criteria are included regardless of language or country of origin. It aims to answer questions about the effectiveness of aromatherapy for PONV in comparison to standard
antiemetic treatments and in comparison to placebo. Studies of both adult and paediatric patients were included.

Cross-sectional survey: The scope of the survey is limited to establishing the validity and reliability of the adapted tool. Data about the beliefs of nurses and midwives is reported in the context of validating the tool. It is not expected that the data provided in the survey will be generalizable to nurses in non-surgical settings or divergent health systems, however the modifications made to the survey instrument in the Delphi process of the pilot study may mean that it can be used to collect data in a variety of settings in the future, thus contributing to the development of an evidence base in this field.

1.4.3 Definitions

Aromatherapy: Aromatherapy refers to the controlled use of plant essences for therapeutic purposes. It can also refer to the use of other scented substances for therapeutic purposes. Literally, the word 'aromatherapy' means 'treatment with scents' and it is believed to act within the olfactory centre of the brain\textsuperscript{13}.

Postoperative nausea and vomiting: Nausea is an abdominal discomfort or queasiness that may be accompanied by vomiting (the forceful expulsion of stomach contents through the mouth). Nausea and vomiting may be produced by either olfactory, visual, vestibular or psychogenic stimuli\textsuperscript{54}; however the main coordinator of the process is the vomiting centre of the brain in the medulla oblongata\textsuperscript{55}. The chemoreceptor zone (CTZ) in the brain stem is particularly implicated in the case of PONV as drugs (particularly narcotics), anaesthetics, and toxins released by the body during surgery reach this area of the brain, nausea and vomiting may occur, which is a protective physiological process as the body attempts to rid itself of toxic substances\textsuperscript{56}.

Midwife: A registered health professional providing care of women during pregnancy, labour, and the postpartum period, as well as care of the newborn\textsuperscript{57}.

Registered Nurse: A fully trained nurse with an official state certificate of competence\textsuperscript{58}.

Systematic review: A secondary research methodology that attempts to identify, appraise and synthesize all the empirical evidence that meets pre-specified eligibility criteria to answer a given research question. Researchers conducting systematic reviews use explicit methods aimed at minimizing bias, in order to produce more reliable findings that can be used to inform decision making\textsuperscript{59}. 

---

Chapter 1: Introduction
1.5 THESIS OUTLINE

Chapter Two reviews the literature on aromatherapy, the treatment of postoperative nausea and vomiting, and nurses’ use, beliefs and attitudes to the use of aromatherapy. Methodology and methods are detailed in Chapter Three. A systematic review of aromatherapy to treat PONV is in Chapter Four. The development of the Nurses’ Beliefs About Aromatherapy Scale (N-BAAS) and the results of testing the adapted tool are described in Chapter Five. Results are analysed and discussed in Chapter Six. Conclusions, recommendations and directions for future research are detailed in Chapter Seven.
Chapter 2: Literature Review

The purpose of this chapter is to review the literature regarding aromatherapy for postoperative nausea and vomiting, both in terms of its efficacy and its use in practice. The usual care of postoperative nausea and vomiting is discussed, as well as aromatherapy for PONV. Theories about the likely mechanism of action of aromatherapy are described. The link between evidence, beliefs about evidence and implementation is discussed. In addition, beliefs and attitudes to the use of complementary and alternative therapies for PONV are examined.

Several electronic databases provided the literature for this chapter. Extensive searches were conducted on Medline, CINAHL, Cochrane Central Register of Controlled Trials (CENTRAL); EMBASE; CAM on PubMed; Meditext; LILACS database (Latin American and Caribbean Health Sciences Literature); and ISI Web of Science. Search terms used included: postoperative, nausea, vomiting, "postoperative nausea and vomiting", recovery, anaesthesia, aromatherapy, phytotherapy, aromatherapy, isopropyl alcohol, peppermint, ginger, complementary, "nursing care", "nurse attitudes", evidence, and implementation. Search terms were generated from preliminary searching of the literature and the keywords of relevant known articles. Google Scholar and Google searches were also conducted. Further articles were identified from the reference lists of retrieved articles.

This chapter begins with a review of the risk factors for postoperative nausea and vomiting (section 2.1) and the study of postoperative nausea and vomiting (section 2.2) and then reviews literature on the following topics: the prevention and treatment of PONV (section 2.3); the mechanism of action of aromatherapy (section 2.4); aromatherapy for PONV (section 2.5) including an examination of the types of substances commonly used to prevent and treat PONV; use of aromatherapy in the general community (section 2.7); and nursing use of aromatherapy (section 2.8). Section 2.10 highlights the implications from the literature and develops the structural framework for the work.

2.1 Risk Factors for Postoperative Nausea and Vomiting

There are three different categories of risk factors for postoperative nausea and vomiting: patient-specific or individual factors, anaesthetic factors, and surgical
factors\textsuperscript{60}. These may interact with and potentiate each other so that the actual risk for some patients to develop PONV may be as high as 70-80%\textsuperscript{4}. Some factors, such as choice of drug or anaesthetic gas can be modified. While some such as length or type of surgery may on occasion be able to be modified, most risk factors cannot.

Several patient-specific risk factors may influence the likelihood of a patient suffering PONV; however a number of these remain the subject of debate as to their clinical importance as signifiers of increased risk\textsuperscript{4, 61, 62}. The most commonly accepted risk factors with the greatest validity for predicting PONV are: female sex, non-smoking, having a prior history of PONV, and postoperative opioid use\textsuperscript{4, 62}. These factors are discussed in further detail below.

The reason for a higher incidence of PONV in women is not well understood\textsuperscript{63, 64}. It has been attributed to hormonal factors\textsuperscript{65}, particularly as the incidence of PONV is no higher in young girls than boys before the age of eight years\textsuperscript{66}. It can be difficult to isolate this as a single factor, as some surgical procedures associated with higher rates of PONV, such as laparoscopic gynaecological surgery, are only performed on women\textsuperscript{4}, but in a study of an orthopaedic procedure on a population of men and women, women were still found to have a far greater risk of PONV\textsuperscript{64}.

The apparent protective action of tobacco smoking for PONV is even less well understood. It has been theorised that the polycyclic hydrocarbons found in tobacco smoke may cause changes in liver enzymes which then act to protect against nausea and vomiting\textsuperscript{67}. Alternately, it may be that there is an inhibitory effect on the serotonin 5-HT\textsubscript{3} receptors\textsuperscript{68}. Other authors have hypothesised that nicotine may be the active agent in tobacco smoke which causes the antiemetic effect\textsuperscript{69}. In a clinical trial of a transdermal nicotine patch to prevent PONV, a significant reduction was seen in former smokers given the patch pre-operatively when compared to a control group of non-smokers ($p < 0.0001$)\textsuperscript{69}. While this is suggestive of a prophylactic effect, it should be remembered that the treatment was applied to former smokers who may have had some lasting change to their physiology due to their past smoking habit. The study was unable to apply the nicotine patch intervention to a group of non-smokers due to ethical concerns\textsuperscript{69}.

Anaesthetic risk factors have been extensively explored in the literature\textsuperscript{2, 6, 70-72}. The use of volatile inhalational anaesthetic gases such as halothane, isoflurane or sevoflurane is strongly associated with PONV\textsuperscript{70}. Propofol, which is used intravenously, does not appear to be as strongly associated with PONV\textsuperscript{73}, but it is not suitable for use in all patients and procedures. A meta-analysis of studies
that included patients undergoing anaesthesia with propofol showed only a small reduction in risk\textsuperscript{74}.

In addition to the individual and anaesthetic risk factors, several different types of surgical procedures are associated with increased risk of PONV. Patients undergoing gynaecological, obstetric, head and neck (including craniotomy), thyroid, laparoscopic and abdominal surgeries have all been reported to have an increased risk of PONV\textsuperscript{72}, although type of surgery has been discounted by Apfel et al.\textsuperscript{4} as a predictor of PONV. It has been argued that the prevalence of female patients in the types of surgery most associated with PONV skews the incidence in favour of these procedures\textsuperscript{4} thus making it difficult to isolate this as an independent risk factor.

2.2 THE STUDY OF POSTOPERATIVE NAUSEA AND VOMITING

PONV can be a difficult phenomenon to study. Much of the effect of treatments for PONV is measured by patient report and the accuracy of this may depend on factors such as the patient's perception of the nausea, their conscious level, their communication skills or ability to understand the tool being used to rate their nausea. Standardised PONV assessment tools are not in wide use; most studies of the severity of PONV utilise a visual analogue scale (VAS) which provides a visual representation of the patient's condition over a numerical range (for example: 0 to 5), or verbal descriptive scale (for example: no nausea, some nausea, very nauseated, retching, vomiting)\textsuperscript{75} but these tools are not frequently used in clinical practice. The accuracy of these scales is highly dependent on the cooperation of an often very unwell patient.

The methodology of studies of PONV have been extensively critiqued by Apfel, et al.\textsuperscript{76}. Among the criticisms of the current state of research in the field, Apfel et al. assert that many studies of the prevention and treatment of PONV are of poor quality, including only early outcomes, poorly delineated definitions of nausea and vomiting, as well as not reporting nausea and vomiting as separate outcomes\textsuperscript{76}. Apfel et al. recommend that wherever feasible PONV should be measured to 24 hours postoperatively\textsuperscript{76}; however none of the studies identified for this review have published such data with most only collecting data for two hours postoperatively.

Few studies of interventions for PONV utilise complete blinding or allocation concealment, despite these procedures being essential to minimise the risk of bias. This is also highlighted by Apfel et al. as a common problem with studies of interventions for PONV\textsuperscript{76}. Consequently, the current body of evidence on
postoperative nausea and vomiting is of variable methodological quality and presents some quite contradictory findings. This will be elaborated in the following sections.

2.3 PREVENTION AND TREATMENT OF POSTOPERATIVE NAUSEA AND VOMITING

A vast number of studies have been published on the prevention and treatment of postoperative nausea and vomiting. As early as 2001 it was estimated that there were at least 27 different systematic reviews on the topic, which included over 430 research studies and 55,000 patients. Evidence and recommendations are sometimes contradictory, but some commonalities are apparent and these are explored below.

Evidence-based guidelines published in 2007 by The Society for Ambulatory Anaesthesia recommend that clinicians: 1) identify at-risk patients; 2) reduce baseline risk; 3) use PONV prophylaxis in one or two interventions for adults at moderate risk; 4) use combination/multi-modal antiemetic therapy in high-risk adults, use prophylactic antiemetics for children, and provide antiemetic therapy to patients who develop PONV.

The identification of at-risk patients has been facilitated by the development of several risk scores. One of the most commonly used risk algorithms is Apfel et al.’s PONV risk score, originally developed in 1998 and further simplified and cross-validated in 1999 using new data from two separate studies. This simplified risk score was further tested and found valid in a study by Pierre et al. in 2002. Other risk assessment tools with a greater number of items have been suggested, but in the development of Apfel et al.’s original risk score these additional risk factors were tested and found to be unnecessary to the prediction of PONV.

Apfel et al.’s risk score uses just four items to calculate the risk of developing PONV: female sex (P < 0.0001, OR = 3.55, 95%CI = 2.46 to 5.14), prior history of PONV or motion sickness (P = 0.0003, OR = 1.91, 95%CI = 1.35 to 2.70), use of postoperative narcotics (P = 0.0002, OR = 2.10, 95%CI = 1.42 to 3.10) and non-smoking (P < 0.0001, OR = 2.05, 95%CI = 1.49–2.82). The incidence of PONV with none of these factors present is 10%, for 1 factor it is 21%, for 2 factors 39%, for 3 factors 61%, and when all 4 factors are present, the risk is 79%.

Reduction of baseline risk is difficult for most patients as the majority of the most reliable risk factors are non-modifiable. The only risk factor from Apfel et al.'s original risk score that can be modified is non-smoking.
al.’s algorithm able to be controlled (use of postoperative narcotics) has the potential for leaving patients with little or no nausea but significant postoperative pain, which is also an undesirable outcome. Nevertheless, modification of analgesic protocols has been recommended, with non-narcotic pain relief such as tramadol and wound infiltration with local anaesthetics being used in preference to narcotics where possible80.

The prevention of PONV is generally considered to be the preferred option for all surgical patients, but particularly for those at moderate to high risk60. Antiemetic prophylaxis with various drugs was explored extensively by Carlisle et al. in their systematic review on the subject51. This review included 737 studies with 103,237 participants, comparing a large number of treatments to other treatments, placebo and no treatment51.

The review found eight drugs which consistently prevent PONV: droperidol, metoclopramide, ondansetron, tropisetron, dolasetron, dexamethasone, cyclizine and granisetron51. It should be added that due to concerns over potentially serious adverse cardiac effects (QT prolongation leading to Torsades de Pointes) droperidol has largely fallen from general use, despite its prescription still being permitted81. Despite these findings, antiemetic prophylaxis appears not to be universally effective. Carlisle estimates that, for high risk patients, universal prophylaxis would result in approximately 28% of those patients not experiencing PONV, and for low risk patients the number would be about 10%51.

Combination therapy for prevention of PONV is recommended by several authors5, 77, 82. While the effects of using more than one drug are greater than for one drug alone, the effects are not simply added for each additional drug51. For example, one study comparing dexamethasone alone to a combination of dexamethasone and metoclopramide showed that while dexamethasone alone reduced the incidence of early PONV to 23.1%, the addition of metoclopramide 50 mg reduced the incidence to 14.5%82. Similar results have been published on combinations of ondansetron and dexamethasone83, dexamethasone, droperidol and ondansetron5, and dexamethasone and ginger84.

In terms of the treatment of existing PONV with antiemetic drugs, there are fewer studies but still some strong evidence. Tramer’s 1997 systematic review85 of ondansetron to treat established PONV showed, in a meta-analysis of nine studies, that ondansetron was effective in providing complete relief of symptoms in approximately one quarter of participants with nausea and/or vomiting (NNT approximately 4). This review’s searches appear quite rudimentary, accessing only one database with a brief list of search terms; however the quality
assessment, data extraction and data analysis processes seem adequate and overall the methods seem acceptable when taken in the context of the year it was conducted.

A later, larger systematic review of a wider range of antiemetics to treat PONV\(^8\) found quite similar results. The well-conducted and reported review by Kazemi-Kjellberg et al. in 2001\(^8\) included 18 placebo-controlled randomised controlled trials with 3809 participants, examining the effectiveness of eight different antiemetic drugs. The absolute risk reduction in the studies able to be combined in this meta-analysis (studies of 5-HT\(_3\) receptor antagonists including ondansetron) was 20-30\% for postoperative vomiting only\(^8\).

It is quite clear from the findings of these two systematic reviews that for a large percentage of patients with PONV, antiemetic drugs will be of little or no benefit. For every 100 patients given a 5-HT\(_3\) receptor antagonist such as tropisetron or ondansetron 70 or 80 will have no relief of their symptoms\(^6\), \(^8\) and require further treatment. Repeat dosing with 5-HT\(_3\) receptor antagonists was found to have minimal effectiveness\(^7\) as there is little dose-response relationship for these drugs\(^9\); however re-dosing of 5-HT\(_3\) receptor antagonists has been found to be routine practice for a significant percentage of anaesthesiologists\(^9\). The majority of anaesthesiologists will prescribe antiemetic drugs from different classes until the patient’s symptoms are relieved\(^9\).

Due, in part, to the lack of efficacy of antiemetic drugs in preventing and treating PONV for a significant percentage of patients, interest in non-pharmacological treatments and complementary therapies has grown. The evidence for use of non-pharmacological techniques for preventing PONV is quite variable. Acupuncture has been studied extensively, as has music therapy, and aromatherapy, both as a treatment and a preventative\(^8\). Due to the potential seen in the research and the incomplete evidence base, I have chosen in this work to focus on aromatherapy as a treatment for postoperative nausea and vomiting.

### 2.4 AROMATHERAPY: MECHANISM OF ACTION

The mechanism of action for aromatherapy is not well understood. Essential oils are reported to have effects at the psychological, physiological and cellular level\(^8\). There are currently no human studies to show that any ingredient from the inhaled vapours of essential oils are present in the blood or plasma\(^8\). Herz’s high quality critique of the current state of aromatherapy science highlights many of the poorly supported claims made about these substances and suggests
that rather than there being a pharmacological action for aromatherapy, it is more likely that aromatherapy’s effects are psychologically or culturally based\textsuperscript{88, 89}. The theory that the action of aromatherapy is pharmacological, Herz suggests, may be disproved by the immediacy of its effect as pharmacological substances require time for absorption within the body (usually a minimum of 20 minutes)\textsuperscript{88}. This position does not take into account the more rapid absorption of inhaled drugs; for example, drugs commonly used to treat asthma begin to take effect as early as five minutes post-administration\textsuperscript{90} and it may be possible that the vapours of essential oils act with similar rapidity.

It has been claimed that the effects of some aromatherapy products are pharmacological\textsuperscript{91} because effects can be seen on various physiological tests, such as electro-encephalograph (EEG)\textsuperscript{92, 93} or other biomarkers\textsuperscript{94}. Studies of aromatherapy for stress, for instance, have demonstrated a measurable reduction in stress hormones as indicated by cortisol levels ($P < 0.05$) and chromogranin A levels ($P < 0.05$) in salivary sampling when lavender and peppermint aromatherapy was given following a stressful event\textsuperscript{94}. But I would argue that these studies are measuring outcomes that reflect exposure to a stimulus and not necessarily positive proof of a pharmacological process. The brain waves measured by EEG are sensitive to a range of states such as alertness, relaxation, rest, hypnosis and sleep\textsuperscript{95}. It may be that the exposure to oils such as lavender\textsuperscript{92, 93} is inducing relaxation, in the way that certain types of environmental exposures do\textsuperscript{96}, without the process being necessarily pharmacological.

One proposed mechanism of action that seems more likely is that the scent activates the olfactory system which in turn triggers the limbic system\textsuperscript{28}. This in turn may produce emotional responses and may enhance the retrieval of learnt memories\textsuperscript{28}. Brain activation associated with emotional response in connection to odour exposure has been recorded on functional MRI imaging, although this was a brief report of a small study with incomplete detailing of its methods and the findings should be taken with due scepticism\textsuperscript{97}. It is known that olfactory pathways reach into the hypothalamus, which may be the route for emotional responses to aromas\textsuperscript{22}. Linalool-producing plant species, such as peppermint, have been shown in animal studies to evoke emotional responses such as aggression in mice exposed to the vapours\textsuperscript{22}. Linalool is a monoterpane alcohol found in aromatic plants\textsuperscript{87} which has been studied for its effects as a sedative, anticonvulsant and hypothermic\textsuperscript{22}.
It is difficult to find high-quality research which replicates the animal findings in humans, and given that response to scent has been shown to be cultural\textsuperscript{89}, able to be influenced by the prompting of researchers\textsuperscript{98}, and dependent on the participant's perception of the scent\textsuperscript{99} it seems likely that the mechanism of action of aromatherapy on humans is more complex or different than its effect on animals.

It also seems likely that the mechanism of action is different for aromatherapy delivered through inhalation or through massage. Essential oils can be absorbed through the skin and some may exert a physiological effect on cellular and organ function\textsuperscript{102, 103}, and this type of absorption is different to the olfactory mechanism of action disputed by Herz\textsuperscript{88}. Recent laboratory studies of animals have shown that some aromatherapy preparations cause observable changes in biochemistry\textsuperscript{100, 101}.

In terms of aromatherapy's action on PONV, peppermint oil has been shown to reduce foaming of gastric fluids in the stomach\textsuperscript{104}, which coupled with peppermint's calcium channel antagonist action on relaxing smooth muscle in the gut\textsuperscript{105} may help to explain its anti-nausea effect. It should be emphasised that only oral administration of peppermint has been shown to have an effect as a smooth muscle relaxant\textsuperscript{104}. No studies were found that showed an equivalent effect for inhaled peppermint vapours.

While isopropyl alcohol has been extensively investigated for use to treat PONV, no studies could be found that suggested a mechanism of action. It has been shown that, unlike essential oils, small but measurable amounts of alcohol can be found in the blood after exposure to alcohol vapours\textsuperscript{106} and it may be that there is some pharmacological action causing the anti-nausea effect. For most types of aromatherapy it seems more likely that the effect on PONV is based on psychological rather than physiological mechanisms of action.

### 2.5 AROMATHERAPY FOR POSTOPERATIVE NAUSEA AND VOMITING

Possibly the single most studied aromatherapy for nausea and vomiting is ginger (\textit{zingiber officinale}). It has been the subject of many randomised controlled trials\textsuperscript{35, 84, 107-111, 37} and several systematic reviews\textsuperscript{33, 36, 112-114}. It is classified as an aromatherapy even though it is frequently given orally\textsuperscript{28}. Studies of ginger are of variable quality, with few well-designed randomised controlled trials able to be identified from the searches. Rigorous studies were less likely to find
evidence of an effect. Well-conducted systematic reviews have not found evidence of a preventative effect for ginger on postoperative nausea or vomiting.

2.5.1 Ginger Versus Placebo for Prevention of PONV

The inverse relationship between positive findings and methodological quality was clearly seen in five randomised controlled trials comparing ginger aromatherapy with placebo\(^37, 107, 110, 111, 113\). All five of these studies enrolled female patients undergoing laparoscopic surgery (n = 548). Studies where methods of randomisation and blinding were not stated explicitly or were poorly described\(^107, 110, 111\) found that ginger was an effective intervention for preventing PONV, while the two studies with well-described methods that included adequate blinding and randomisation\(^37, 113\) were unable to find any evidence of an effect.

The two more rigorous studies\(^37, 113\) were also unable to find any dose–response relationship. Regression analysis in the study by Arfeen et al. showed that nausea scores were not significantly associated with ginger dose (P = 0.47) and further analysis of covariates with known risk factors such as history of PONV or opioids received did not change the finding\(^37\). Similarly, the study by Eberhardt et al. found no significant difference in PONV incidence between the three groups at the conclusion of the study (P = 0.69) for ginger dosages between 0 and 600 milligrams\(^113\).

On the strength of this evidence, it seems unlikely that ginger is a more effective antiemetic than placebo for patients for preventing PONV in this high-risk group.

2.5.2 Ginger versus Pharmacological Antiemetics for Prevention of PONV

Similarly, for the five studies\(^35, 84, 108, 109, 115\) comparing ginger with antiemetic drugs for preventing PONV, incompletely reported methods were associated with more positive findings of an effect. Overall studies of this comparison (ginger versus pharmacological antiemetics) were more rigorous and had a higher standard of reporting than those in the previous comparison (section 2.5.1). Follow-up was done to 24 hours in one study\(^84\) and to 48 hours in another\(^108\), which may also increase the validity of the findings. Blinding of outcome assessors was explicitly undertaken by three studies\(^84, 109, 115\) and this again was associated with findings of no significant effect.

Antiemetic drugs used as comparisons in these studies were metoclopramide\(^35, 108, 115\), prochlorperazine\(^108\), promethazine\(^108\), dexamethasone\(^84\), droperidol\(^109\) and ondansetron\(^108\). Of these, ginger approached but did not exceed a level of effectiveness similar to metoclopramide in two studies\(^35, 115\), which while this is
not a statistically significant finding could be clinically important if an antiemetic is required and metoclopramide cannot be used.

Ginger was not found to be more effective than any of the other antiemetic drugs for preventing PONV in these studies. When the wide range of drugs represented and the strength of the designs for some studies, it seems unlikely that further studies will make very different findings from those outlined here.

### 2.6 SYSTEMATIC REVIEWS OF GINGER FOR PREVENTION OF PONV

Five systematic reviews have examined the effectiveness of ginger for postoperative nausea and vomiting\(^{33, 36, 51, 112, 114}\). The methodological quality of these reviews is variable; however there are some that have utilised rigorous methods, and the methods and findings of these systematic reviews are detailed and critiqued below.

The first systematic review of ginger to prevent PONV was conducted by Ernst and Pittler in 2000\(^{33}\). This review examined a range of nausea and vomiting conditions, but for this literature review I will only discuss those related to PONV. The Jadad Scale was used to critically appraise each trial and the majority of included studies were scored 3/5 (moderate quality)\(^{33}\). Six studies were included in the final review, and three of these were relevant to PONV\(^{33}\).

The data from these three trials were pooled in a statistical meta-analysis and reported as absolute risk reduction (ARR)\(^{33}\). The pooled ARR for the incidence of PONV showed no significant difference between the group treated with ginger 1 gram preoperatively and the placebo group (ARR 0.052, 95%CI 0.082 to 0.186)\(^{33}\). The authors highlight the small amounts of data able to be included as a weakness of this review and the findings should be read in that context\(^{33}\).

In 2004 Morin and Betz et al. conducted a systematic review of the effectiveness of ginger to prevent PONV\(^ {114}\). This review included 6 studies with 538 participants\(^ {114}\). Searches were conducted in December 2003\(^ {114}\). Only the Medline, Embase and Cochrane Trials databases were searched, and the languages used were not stated\(^ {114}\). Critical appraisal was conducted using the Oxford Quality Score (also known as the Jadad Scale\(^ {116}\)) and individual quality scores are reported for each study\(^ {114}\). The majority of included studies were scored three out of a possible five points on the Jadad Scale\(^ {114}\) indicating moderate methodological quality.

For combined postoperative nausea and vomiting outcomes (for 538 participants) no preventative effect was seen. Morin and Betz et al. report a
pooled relative risk (RR) of 0.84 (95% CI 0.69-1.03) and a Number Needed to Treat (NNT) of 11\textsuperscript{114}. Meta-analysis of studies reporting rescue antiemetic use showed a RR of 0.76 (95% CI 0.37-1.55) and a NNT of 17, which again, shows no evidence of an effect\textsuperscript{114}.

It is unclear to what purpose the above author group conducted a second systematic review\textsuperscript{112} on the same topic published the following year (Betz, et al., 2005) except perhaps to broaden slightly the review question to include a wider range of studies. As this is obviously a different review with a different number of included studies and participants and not a re-publication, it has been included here for reasons of completeness. This second systematic review (Betz et al.) again examined the antiemetic use of ginger, this time including 15 studies with 777 participants\textsuperscript{112}. Again, only the Medline, Embase and Cochrane Trials databases were searched, and the languages used were not stated\textsuperscript{112}. Searches were conducted in July 2003\textsuperscript{112}. Critical appraisal of studies was conducted with the Jadad Scale\textsuperscript{112}. Included study quality ranged from 3-5 out of a possible 5 points\textsuperscript{112}.

Betz et al.’s review\textsuperscript{112} found that the meta-analysis of higher quality studies (Jadad Score 4 & 5)\textsuperscript{37, 109, 113} showed no evidence of a preventative effect (P = 0.94, RR = 0.01, 95% CI 0.79 to 1.29). In contrast, a meta-analysis of the lower quality studies (Jadad Score 3)\textsuperscript{35, 111, 115} found quite strong evidence of an effect (P = 0.002, RR = 0.65, 95% CI 0.49 to 0.96). This appears to be an expansion of the prior review\textsuperscript{114} by this author group and so the findings should be considered as a repeated analysis and not truly additional evidence, except for the few studies not included in the 2004 review. Nonetheless, it does clearly illustrate the prevailing trend for lower quality studies to show stronger evidence of an effect.

Chaiyakunapruk et al. conducted a further systematic review of the efficacy of ginger to prevent postoperative nausea and vomiting with more rigorous review methods in 2006\textsuperscript{36}. Searches were conducted with no language restriction and more comprehensive than the previous reviews, accessing a larger number of databases\textsuperscript{36}. Inclusion criteria were more stringent than the previous reviews, with only randomised, placebo-controlled controlled trials of 1 gram or more of ginger, reporting PONV outcomes at least to 24 hours being eligible\textsuperscript{36}. The Jadad Scale was used to critically appraise study quality and included studies were scored at 3 and four out of a possible five points, indicating moderate to high quality\textsuperscript{36}. Five studies\textsuperscript{35, 111, 113, 115, 117} involving 363 participants were eventually included in the analysis\textsuperscript{36}.
Interestingly, this review found quite different results to the two previous reviews, despite including many of the same studies. Unique to this review was the inclusion of the unpublished Master’s thesis by Jannam117 and it is of concern that no sensitivity analysis was performed to judge the effect exerted on the analysis by this study. Sensitivity analysis was performed with and without the inclusion of the study by Eberhart et al.113 as the review authors were of the opinion this study did not meet their inclusion criteria due to the experimental dose sizes (300 milligrams and 600 milligrams)36. This is open to dispute as participants in the experimental groups in Eberhart et al.’s study actually received three doses of 300 or 600 mg of ginger113, making the dose administered to the 600 mg group (1.8g) well within the inclusion criteria. No evidence of an effect was seen in the combination of all studies including Eberhart et al. (pooled RR 0.74 (95%CI 0.56 to 0.98))36, though it is unclear whether they included all the data from Eberhart et al. or only the data from the group within their inclusion criteria. The authors conclude they have shown ginger to be a clinically effective antiemetic; however this seems debatable.

Certainly when ginger was subjected to rigorous systematic review in the 2006 Cochrane review of ‘Drugs to Prevent Postoperative Nausea and Vomiting’ by Carlisle and Stevenson51 no evidence of an effect was found for preventing either postoperative nausea or vomiting (RR 0.79, 95%CI 0.55-1.14). This well-conducted systematic review performed searches of a wide range of databases without language restriction, utilised the standard Cochrane Risk of Bias tool to assess risk of bias in included studies, and extracted data according to standard Cochrane methods. While this systematic review does include studies by Fujii that were subsequently retracted118, its validity has been preserved by performing sensitivity analysis with and without the suspect data.

As can be seen from the above studies and systematic reviews, ginger as a preventative against PONV has been studied extensively. As there has been no convincing evidence of an effect found by high quality studies and systematic reviews, it seems unlikely that further studies of this substance for PONV will produce evidence of significant effects. No studies were found that examined the use of ginger to treat established PONV.

2.6.1 Essential Oil Mixtures to Prevent and Treat PONV

A handful of essential oils have been scientifically studied as treatments for PONV and as yet, no clear evidence on the benefits of any of these has emerged.
A non-randomised trial of a mixture of three essential oils to prevent PONV was conducted in France\textsuperscript{119}. A total of 73 participants were included in the study\textsuperscript{119}. The methods of recruitment, allocation and any blinding or concealment are not described. A mixture of cardamom, tarragon and ginger oil was applied to participants’ skin, on the neck, when they complained of nausea\textsuperscript{119}. Of the 73 participants with PONV, 50 were reported to have experienced complete cessation of symptoms within 30 minutes of treatment\textsuperscript{119}, an effect size so large as to invite scepticism, particularly in light of the lack of description of scientific methods used.

Two studies examined a novel aromatherapy delivery system (Quease Ease\textsuperscript{TM}) to treat PONV using a mixture of lavender, peppermint, spearmint, and ginger essential oils in an inhaler designed for self-administration by patients\textsuperscript{120, 121}. The prospective randomised study by Hodge et al.\textsuperscript{121} appears more rigorously designed but still suffers from inadequate detail in the brief published report. Both studies found this intervention to be effective and well-accepted by patients. Neither study is well-described or was published in a peer-reviewed journal, making it difficult to substantiate the claims of effectiveness in both papers. Both these studies were examining the effectiveness of the product for treatment of PONV, but there is insufficient published data to enable assessment of their methodological quality and the rigour of their findings.

On the basis of these three studies there is no evidence of the effectiveness of these essential oil mixtures for preventing or treating PONV.

### 2.6.2 Peppermint Oil for the Treatment of PONV

Somewhat more reliable research is found in studies of peppermint oil for PONV.

A small trial of 18 participants used a 3-group design to test the effectiveness of inhaled peppermint oil vapours to treat PONV\textsuperscript{14}. While the study reports significant evidence of an effect and is one of the most often cited texts on the subject, it is difficult to substantiate this. The study reports that participants receiving peppermint oil experienced significantly fewer nausea episodes and had lower average daily nausea scores than the placebo/sham treatment group who received peppermint essence\textsuperscript{14}. While this does appear to be the case, the published graphs indicate that the usual care group actually had the lowest average scores on both the operative day and postoperative day two of the study, with the peppermint oil group only achieving the lowest scores of all groups on postoperative day one\textsuperscript{14}. In comparison to the placebo/sham treatment group, the peppermint oil group is reported to have substantially
lower average daily nausea scores. It is not possible, from the findings presented in this study and the size of the sample, to make any kind of definitive statement about the effectiveness of this therapy.

Anderson and Gross also conducted a three-arm randomised controlled trial to further test this therapy. This well-reported study randomised 33 ambulatory surgery patients to receive either peppermint oil, isopropyl alcohol (IPA) or normal saline on a gauze pad which was given to them to smell when they complained of nausea in the recovery room after surgery. Randomisation was conducted with the use of a computer generated random numbers table. Nausea was scored with the use of a 100mm VAS at 2 minutes and 5 minutes after the treatment. These short time points are of concern in the light of Apfel et al.’s recommendations for studying PONV, which recommend measures continue to at least 24 hours. There were no significant differences between the groups in any of the reported demographic or medical history factors. There were also no significant differences in the nausea reported by each of the three groups of participants at each time point, although the scores for all groups did decrease at each subsequent measurement.

On the basis of these two studies it is not possible to conclude that peppermint oil is an effective treatment for PONV. These studies are further examined in Chapter Four.

2.6.3 Isopropyl Alcohol to Treat Postoperative Nausea and Vomiting

There is a range of studies of varying quality examining the effectiveness of isopropyl alcohol (IPA) for treating PONV. These began to appear in 1997 with the publication of Langevin and Brown’s small trial. The only published data available on this trial is in the form of a conference abstract and attempts to contact the authors for further data were unsuccessful. This double-blinded, cross-over study randomised fifteen surgical patients to receive either inhaled IPA vapours or a normal saline placebo on first complaint of nausea and then if nausea persisted, the alternate treatment was given. Nausea was measured on a 10-point Visual Analogue Scale (VAS), first on complaint of nausea and then every five minutes until discharge from the recovery room. IPA was reported to have caused complete relief of symptoms in 80% of all participants (n = 12). No further statistical analysis of these results is reported.

Following on from this study, Wang et al. trialled IPA’s effectiveness in a group of children undergoing day surgery procedures. Thirty-nine children aged 6-16 years were randomised to receive either IPA or saline placebo when they...
complained of nausea or vomiting in the recovery room. Randomisation was conducted using a random number table and blinding was attempted through instructing the nurses who were delivering the treatment not to smell the cotton swabs containing the substances. Nausea was measured on a 100mm VAS on first complaint of nausea and at 5 minute intervals thereafter until discharge from the unit or recurrence of symptoms. Treatment was repeated a maximum of three times in a 15 minute period. Rescue antiemetics were provided to participants who continued to complain of PONV.

After receiving three treatment sequences, 91% of the treatment group and 40% of the placebo group reported full relief of their nausea symptoms (P < 0.05). The results for children with vomiting were less compelling, with 33% of the treatment group and 11% of the placebo group gaining relief. This effect was reported to be transitory, with 54% of participants experiencing a recurrence of symptoms after initial relief. As this is the only study of children found, it is not possible to state with certainty whether this phenomenon would be repeated in other children given IPA for PONV, but these results are suggestive of a difference in the response to this therapy between children and adults.

In 2002, Kamalipour and Parviz randomised 82 (34 men/ 48 women) surgical patients to receive either 0.5 millilitres of either normal saline or IPA on first complaint of nausea in the recovery room. Participants were asked to inhale from the gauze containing the study substances and their response to the treatment was recorded, although how this was measured is not reported. Methods of randomisation, allocation and blinding were not described. Participants not responding to the initial treatment received a second dose, and those who still did not respond were given a rescue antiemetic (metoclopramide). The methods of this study are quite poorly described, as are the findings. The study reports that of 41 participants in the IPA group, 32 (78%) "responded positively" to the initial treatment (definition of response not provided) and in the control group only 3 participants "responded positively". This, if accurate, represents an effect size which, while similar to the earlier study by Langevin and Brown, seems disproportionately large in comparison to other, more completely reported studies.

In the same year, Merritt et al. published their quasi-experimental trial of IPA insufflation (inhalation of vapours) to treat PONV. Thirty-nine surgical patients with complaints of PONV were recruited to the study, with alternate days indicating whether experimental or control treatment was given. The authors...
state that this allocation method was used to preserve blinding between the groups\textsuperscript{40}. Nausea was measured on a Descriptive Ordinal Scale (DOS) from 0 (no nausea) to 10 (worst nausea or vomiting imaginable) every five minutes from first complaint of nausea\textsuperscript{40}.

Participants in each group were not significantly different in terms of demography, anaesthesia type or surgical procedure\textsuperscript{40}. Rescue antiemetics were given in both groups if initial treatment failed to give relief\textsuperscript{40}. Both treatment and control groups had comparable baseline nausea scores and following treatment, both groups remained very similar with mean DOS of 2.7 (SD: 3.02) (indicating mild nausea) in the treatment group and slightly lower at 1.94 (SD:2.48) for the control group\textsuperscript{40}. Interestingly, the authors claim their results parallel those of Langevin and Brown\textsuperscript{40}, but it is difficult to see where they do, as the decrease in nausea scores is quite uniform across both experimental and control groups, whereas Langevin and Brown reported a very large effect in their experimental group\textsuperscript{39}.

The following three studies were conducted in the same facility by some of the same authors and so share several features. Some unpublished data was provided by an author on all three studies (Pellegrini) to enable the meta-analysis in Chapter 4 and this will be used to inform this discussion. The studies which all have unique strengths and weaknesses will be discussed separately, and where appropriate will be synthesised in the systematic review in Chapter 4.

In contrast to previous studies which compared IPA to placebo, Winston et al. conducted a trial comparing the effectiveness of IPA to ondansetron, a widely used 5-HT\textsubscript{3} inhibitor class antiemetic\textsuperscript{18}. For this study, 100 women were randomised, preoperatively, to receive either IPA or ondansetron, subsequently, 41 of those actually experienced PONV (29 in the IPA group, 12 in the ondansetron group) and were included in the analysis\textsuperscript{18}. In the ondansetron (control) group at first request for treatment participants received intravenous ondansetron 4 milligrams, repeated once in 15 minutes if required\textsuperscript{18}. Participants in the IPA group received a standard 70\% alcohol prep-pad held under her nose with instructions to take 3 consecutive deep breaths\textsuperscript{18}.

For early time points (five and ten minutes) the IPA group reported significantly fewer nausea events than the ondansetron group (P = 0.002 and P = 0.015 respectively), but for time points exceeding those, no significant effect was seen and there was little difference between the groups\textsuperscript{18}. Significantly though, the mean time to 50\% reduction in nausea scores was much less in the IPA group.
(6.3. versus 27.7 minutes), which would seem to indicate that this is a therapy worth further investigation.\textsuperscript{18}

In Cotton et al.’s prospective randomised study of IPA insufflation compared to IV ondansetron for treating PONV, 100 women aged 18-65 who were scheduled for laparoscopic same-day surgery were recruited and randomised, using computer generated block randomisation, to receive either ondansetron 4 mg IV every 15 minutes to a maximum 8 mg dose or a folded alcohol pad held approximately a ‘1/2 inch’ from the participant’s nares with the instruction to take three deep breaths in and out through the nose.\textsuperscript{17} Allocation was concealed, although it does not seem that blinding was undertaken. Time, dose and nausea, as measured on a Visual Numeric Rating Scale (range 0-10 where 0 = no nausea and 10 = worst imaginable nausea), were recorded. Breakthrough PONV was treated with promethazine suppositories for both groups. Participants were also given supplies of IPA and promethazine to use as needed at home after discharge and asked to record any occurrences of PONV with a data collection tool provided by the researchers.\textsuperscript{17}

The main reported outcome was time in minutes to 50% reduction in VNRS. After first complaint of nausea the ondansetron group required a mean of 33.88 minutes (SD: 23.2 minutes) to achieve a 50% reduction in VNRS scores compared with 15.00 minutes (SD: 10.6 minutes) for IPA group (P = 0.011).\textsuperscript{17} At the second treatment for complaints of PONV, a significant difference also was also seen; ondansetron group subjects required a mean time of 26.25 minutes (SD: 7.5 minutes) to achieve 50% relief, compared with 15.00 minutes (SD: 5.25 minutes for the IPA group (P = 0.013). While these times are somewhat greater than those found by Winston et al., they still show a considerable effect in comparison to one of the most popular antiemetic drugs.

Pellegrini et al. then followed these studies with a randomised controlled trial comparing 70% isopropyl alcohol insufflation to promethazine to treat breakthrough nausea in surgical patients at high risk of PONV. Eighty-five surgical patients scheduled for general anaesthesia of more than 60 minutes’ duration who had at least two of the main risk factors for developing PONV were randomised into two groups. Groups were not significantly different across demography, treatment or history. The IPA group (n = 42) received the same treatment as described above in Cotton et al. and the control group (n = 43) received 12.5 to 25 milligram IV promethazine for complaints of PONV in the recovery room or same-day surgery (SDSU) and promethazine suppository for self-administration following discharge to home. Nausea was measured with
Verbal Numeric Rating Scale (VNRS) (0-10, 0 = no nausea 10 = worst nausea imaginable) and the number of nausea events were counted\(^{19}\). The main outcome of interest was time in minutes to 50% reduction in the VNRS\(^{19}\).

A total of 85 participants were included in the final analysis\(^{19}\). There was no significant difference between the groups in terms of incidence of postoperative nausea events (\(P = 0.119\))\(^{19}\). The study reports that 50% reduction in VNRS scores were achieved in the IPA group significantly more quickly compared with the promethazine group in recovery (\(P = 0.045\)), SDSU (\(P = 0.032\)), and the home (\(P = 0.017\))\(^{19}\). Unfortunately, it is likely that this study was confounded due to all participants having received antiemetic prophylaxis prior to surgery, which is likely to have affected the reliability of this otherwise well-conducted study.

Although the findings of studies of isopropyl alcohol are not uniformly reliable, there is enough evidence of an effect to warrant further examination and these studies and others are included in the systematic review in Chapter Four.

### 2.7 USE OF AROMATHERAPY

Aromatherapy is reported to be a widely used and popular complementary therapy in the general population of many countries\(^{123-127}\). Surveys of the use of complementary therapies name aromatherapy as one of the most frequently used in younger people\(^{128}\), older people\(^{125}\), cancer patients\(^{126}\), in rural\(^{129}\) and urban populations\(^{130}\). Aromatherapy is most often used by women\(^{125, 126, 128, 129}\) in all studies measuring this outcome, which may be related to the finding that women are generally more sensitive to odours than men\(^{88}\).

A slightly dated systematic review of the prevalence of complementary therapy use from 2000\(^{127}\) analysed and summarised the research on the prevalence of use around the world up to 1999 and found significant use reported by studies conducted in high-income countries such as Australia and the USA (40-50% of population). The systematic review may have been confounded by the poor scope of the search methods used (only two databases searched) and the lack of validated quality assessment for the included studies. Despite the methodological issues of this systematic review\(^{127}\) searches have revealed no follow-up or update on this work so it is not possible to accurately estimate the current prevalence of complementary therapy usage. Also, as this systematic review explicitly excluded studies of single complementary therapies, no aromatherapy-specific data are included\(^{127}\).
The reasons individuals use aromatherapy are complex and varied. Respondents with back pain, chronic pain, anxiety and urinary problems in one survey were found most likely to use complementary therapies particularly if they were well-educated, a “cultural creative” or had a “holistic” personal philosophy. While these results are interesting and the survey was otherwise well-conducted, this study’s sample is largely white and well-educated, which is not representative of the population at large. Other work highlights a dissatisfaction with conventional medicine as a driving factor towards the use of complementary therapies.

Patients with diabetes in a small focus group (n = 10) reported a high rate of complementary therapy use, including aromatherapy. The majority of participants were not using complementary therapies to control their blood glucose levels but to treat physical and psychological symptoms as an adjunct to conventional treatments. This non-random sample is too small to make any kind of generalisation to the larger population of people with diabetes, but it nevertheless highlights an important consideration, that patients often use complementary therapies, including aromatherapy, as part of holistic self-care of their condition which encompasses their physical and mental well-being and quality of life.

Interesting, in terms of this work, is the study by Fewell on self-care activities for post-discharge nausea and vomiting (i.e. PONV that occurs after discharge from hospital) which found that of all the strategies patients utilise to treat this problem, aromatherapy was not listed. Participants in this well-conducted cross-sectional study used a variety of non-pharmacological strategies to ease their nausea and vomiting, but aromatherapy was not among them. The author does not speculate or elaborate on any possible reasons for this, but it is likely that the use of aromatherapy to treat PONV or post-discharge nausea and vomiting is not widely known in the community. The link between patients’ use of aromatherapy and nursing use was not investigated by these studies but is examined in Section 2.8.

### 2.8 NURSING USE OF AROMATHERAPY IN CLINICAL PRACTICE

Although it seems likely that there is evidence for the use of some aromatherapy to treat postoperative nausea and vomiting, unless clinicians are aware of and convinced by this evidence, it is unlikely they will choose to use it with their patients. Several authors have examined nurses' opinions, perceptions and use of complementary therapies, including aromatherapy. There were no studies...
found that solely examined nurses’ opinions about, use of, or experience with aromatherapy, although the studies below do include various details about nursing use of aromatherapy.

A survey of 832 nurses in Australia aimed to describe their experiences with complementary therapies, both as a user and as a health practitioner\textsuperscript{43}. Slightly less than half the respondents reported they had used aromatherapy, personally or professionally in the past year\textsuperscript{43}. Twenty-one percent had used aromatherapy with a patient, which was the highest result for any complementary therapy in the survey\textsuperscript{43}. This rate is considerably higher than the usage reported by US nurses\textsuperscript{46}; however this may be due to cultural or healthcare system differences. This large and frequently cited survey describes its methods only briefly, but no major methodological flaws could be identified from the published report.

A second Australian study also explored nurses’ utilisation of complementary therapies\textsuperscript{44}. This smaller study surveyed nurses at hospitals in south-east Queensland (Australia) regarding their use of a range of complementary therapies, including aromatherapy, which 15.5\% answered that they used\textsuperscript{44}. Interestingly, while 80\% of respondents used complementary therapies for themselves, three-quarters of these reported they did not use them in their clinical practice, giving such reasons as lack of resources, lack of organisational policies, and “unable to”\textsuperscript{44}. Few nurses in the survey had complementary medicine qualifications or education themselves, although 22\% had referred patients to complementary therapy practitioners in the past\textsuperscript{44}. Unfortunately, the sampling methods used in this study throw its findings into some doubt as some participants were asked by senior nursing management to participate, some were ‘nominated’ to participate and some volunteered in response to advertising\textsuperscript{44}. It is unclear from the reporting of this study whether these different recruitment methods had any impact on the results of the different groups.

Nurses working in medical areas, e.g. aged care, palliative care and general medicine were significantly more likely to use complementary therapies than those in areas such as midwifery, surgical wards or paediatrics (P = 0.02)\textsuperscript{44}. There was no difference in use between university and non-university educated nurses, or male and female\textsuperscript{44}. Many respondents appeared to regard the use of complementary therapies as "part of the job" particularly for therapies such as massage\textsuperscript{44}. Rates of aromatherapy use in this study are considerably lower than those found by Wilkinson et al.\textsuperscript{43} and the authors speculate this difference may be due to a lack of knowledge and education about complementary therapies\textsuperscript{44}.
A third survey was conducted in England to examine nurses' practices, understanding and experiences of complementary therapies\textsuperscript{45}. Of the 1500 surveys sent, 165 were returned and formed the basis for the analysis\textsuperscript{45}. Of interest to this literature review is the finding that 33\% had heard of aromatherapy, although none answered that they were using it in their practice area\textsuperscript{45}. Some nurses did indicate they viewed complementary therapies as an 'alternative to drugs' and that they could be useful for symptom relief\textsuperscript{45}, which is also relevant to this work. As in the previous survey, very few respondents (n = 8) had any formal training or qualification in complementary therapies\textsuperscript{45}. The lack of an evidence base for complementary therapies was also highlighted as a problem in terms of justifying their use in practice\textsuperscript{45}.

An older study conducted in the US in 2000 examined nurses' self-rating of their knowledge, perceived efficacy, and utilisation of complementary therapies \textsuperscript{46}. The study also utilised a survey design to collect data from 467 respondents (428 female/ 22 male/ 17 declined to answer)\textsuperscript{46}. Nurses were asked to rank the complementary therapies they used personally, professionally, and in terms of referrals of patients\textsuperscript{46}. The survey also used a 5-point Likert scale to gauge responses to six opinion items about complementary therapies\textsuperscript{46}. Importantly, respondents felt that complementary therapies not tested scientifically should not be used, but an even greater number agreed that complementary therapies were a useful adjunct to medical treatments\textsuperscript{46}. Only 97 of the total number of respondents answered that they personally used aromatherapy, making it the eighth most frequently personally used complementary therapy and 23 replied they used aromatherapy with patients/clients, ranking this ninth\textsuperscript{46}. Lack of knowledge of complementary therapies among nurses was highlighted by the authors as a major barrier to wider and more informed use\textsuperscript{46}. It should be noted this study included many items not widely considered to be complementary therapies, such as diet and prayer\textsuperscript{46}, which should be taken into account when evaluating these results.

The final survey was conducted in Taiwan, amongst Bachelor of Nursing students in a university\textsuperscript{47}. Utilising an instrument based on the one developed and piloted by Wallis et al.\textsuperscript{44} above, Chu and Wallis surveyed 170 (168 female/ 2 male) Taiwanese nursing students between the ages of 25 and 55\textsuperscript{44}. Participants were asked to give their opinion about the usefulness of 15 different complementary therapies (in terms of healthcare), in addition to answering a number of demographic questions\textsuperscript{47}.
In relation to aromatherapy specifically, 78.8% of respondents either agreed or strongly agreed that it would be helpful to patients in mainstream healthcare and 27% used it in their nursing practice\(^4\). There were no associations between practice area and use of complementary therapies, unlike Wallis' study of Australian nurses\(^4\). There were similar results regarding the barriers to use, with lack of organisational policies and resources once more being highlighted as crucial roadblocks to wider use of these therapies\(^4\). As with all studies that use self-selecting samples, surveys carry with them an increased risk of bias and so the above findings should all be considered in that context.

### 2.9 USE OF EVIDENCE IN PRACTICE

A key factor in the successful implementation of any new healthcare intervention is the beliefs that clinicians hold about its benefits and utility\(^{134, 135}\). It is not the only influencing factor but, along with organisational and contextual factors, it is important\(^{135}\). The first two steps in the diffusion of innovation as described by Rogers\(^{136}\) are knowledge and persuasion. In the context of this work I am seeking to generate evidence to provide a basis for knowledge and to modify a tool to make it suitable to determine clinicians’ beliefs in order to understand how likely they are to be persuaded by this evidence.

The reasons why some healthcare evidence is readily implemented into practice and some is not, is the subject of much enquiry. Different theories abound in the implementation literature as to how and why evidence is implemented. It is likely that successful implementation depends on a complex web of factors that vary from setting to setting. A common thread between several writers, however, is a recognition that perceptions or beliefs about the nature of the evidence matter\(^{134-136}\).

Practice change is facilitated more easily when the end users believe the change to be useful, beneficial, and practical\(^{134}\). While it is important that the evidence is good quality, for reasons of scientific rigour and beneficence to patients, high quality evidence may be difficult to implement if it is not congruent with clinicians’ beliefs\(^{135}\). Even low quality evidence may be more easily implemented if the potential users have positive beliefs about it\(^{135}\).

Positive staff attitudes and beliefs about the nature of the evidence have been found to be an important facilitator of translating evidence into practice at the individual level\(^{134}\). Nursing staff interviewed in Ploeg et al.’s qualitative study expressed that positive beliefs about the proposed change in terms of patient outcomes and working conditions encouraged them to integrate the changes into
their practice\textsuperscript{134}. Positive beliefs are not the sole mediator of willingness to implement evidence-based practice, but at the level of the individual practitioner and the work culture, they are a vital element\textsuperscript{137}.

In the PARIHS framework described by Rycroft-Malone et al., evidence implementation is constructed as a function of the relationship between three elements: evidence, context, and facilitation; and the relative strength or weakness of each element\textsuperscript{138}. Strength of the evidence is defined as both the scientific robustness of the research, and the degree to which it matches professional consensus and patient preferences. Both professional consensus and patient preference may be interpreted as being concerned with the beliefs of the end users of the evidence. In terms of this work, scientific robustness is being investigated through the conduct of the systematic review to provide strong evidence on the effectiveness of aromatherapy for PONV, and professional consensus through the adaptation of a tool to measure nurses’ and midwives’ beliefs about using aromatherapy in practice.

2.10 SUMMARY AND IMPLICATIONS

PONV is a common postoperative complication affecting approximately 30\% of all patients and up to 80\% of high-risk patients\textsuperscript{139}. Many pharmacological treatments exist and are in wide clinical use but not all patients obtain relief with these drugs. Aromatherapy is a popular complementary therapy\textsuperscript{124} with the potential to add to the number of effective treatments available to treat PONV. It is a simple therapy for clinicians to provide, and it has few reported adverse effects.

There is a gap in the current body of literature, as the true clinical effectiveness of aromatherapy for treating PONV is unknown. Systematic reviews of effectiveness, such as those using the methods developed by the Cochrane Collaboration are considered the ‘gold standard’ of evidence\textsuperscript{53}. The completion of a systematic review on the subject of aromatherapy to treat PONV, utilising the rigorous methods of Cochrane, provides a stronger statement of effectiveness than has previously been available. As seen above, there is some strong evidence on the effectiveness of aromatherapy to prevent PONV in the systematic review by Carlisle and Stevenson\textsuperscript{51} but this review does not include evidence on aromatherapy to treat PONV.

A finding of effectiveness is not all that is required to stimulate the use of a particular intervention. Healthcare is rife with effective, yet under-utilised interventions, because for an intervention to be accepted and used to its full
potential, it needs to be both effective and appropriate – that is, accepted by both patients and clinicians\textsuperscript{140}. While there is significant work on consumer use and acceptance of aromatherapy\textsuperscript{123, 124}; there is little literature on nurses’ beliefs and attitudes to it.

The successful implementation of any new healthcare intervention relies, in large part on the beliefs that clinicians hold about its benefits and utility\textsuperscript{134, 135}. Without positive beliefs about the proposed intervention, it is unlikely to be integrated into practice\textsuperscript{135}. Therefore, when considering the introduction of a novel therapy such as aromatherapy for PONV, it is important to know not only if it works, but what potential users believe about it.

Due to this combination of factors this work undertook both a Cochrane systematic review of the evidence for the use of aromatherapy to treat PONV and a survey of nurses’ beliefs about using aromatherapy. Through this two-pronged approach, studying both effectiveness and appropriateness, the basis is laid for the evidence-based introduction of this therapy in practice. Chapter Three will detail the methods used to achieve these aims.
Chapter 3: Methods

This chapter describes the design adopted by this research to achieve the aims and objectives stated in section 1.3.1 of Chapter 1, that is, to evaluate and synthesise the current best evidence on aromatherapy for PONV, and to modify and test a tool to assess beliefs about aromatherapy. The first objective was the completion and publication of a Cochrane systematic review on the topic to provide evidence for clinicians in a widely available and influential publication and the methods for this are detailed in Chapter 4. The second objective was to modify an existing survey instrument to enable assessment of nurses’ beliefs about the use of aromatherapy in practice and then use psychometric methods to validate this modified instrument and thus fill a gap in the current body of research.

Section 3.1 describes the setting in which the research was conducted. Section 3.3 discusses the methodology used in the Delphi process to modify and validate the Beliefs About Aromatherapy Scale, the stages by which the methodology was implemented, and the research design; section 3.3.3 details the participants in the Delphi process; section 3.3.4 describes the instrument used in the Delphi process; section 3.3.5 discusses how the data was analysed.

Section 3.4 discusses the methodology used to test the modified scale, the stages by which the methodology was implemented, and the research design; section 3.4.3 details the participants in the survey; section 3.4.4 lists the instruments used in the survey; section 3.4.5 discusses how the data was analysed.

Section 3.5 discusses the ethical considerations of the research. Health and safety considerations are discussed in section 3.6.

3.1 SETTING

This research was conducted in a large tertiary health service comprised of several inner-city Australian hospitals providing adults’ public and private care, maternity care, children’s public and private services and a regional hospital providing adult medical and surgical services. Surveys were distributed in five maternity care wards, two intensive care units, two day surgery units, two public surgical wards, three private surgical wards, two regional hospital surgery wards, and four paediatric wards.
3.2 METHODOLOGY AND RESEARCH DESIGN

This work was a two-part process, involving a Cochrane systematic review to establish an evidence-base for use of aromatherapy for post-operative nausea and vomiting, and then conducting a study to modify and test an aromatherapy beliefs tool using a modified Delphi process to make it more relevant to nursing and midwifery practice, and then testing the modified tool with a group of nurses and midwives. The methodology of the Cochrane systematic review is described in Chapter 4. The methodology of the Delphi process and survey are described below.

3.3 DELPHI PROCESS

3.3.1 Methodology

The Delphi process, or technique as it is sometimes known, is well-suited to ascertaining experts’ views on best practice in healthcare. This technique is a useful method for obtaining agreement across a range of views and opinions. The Delphi methodology uses three basic steps to obtain opinions from an identified panel of experts: 1) the expert panel is repeatedly questioned; 2) members of the expert panel do not interact with each other; 3) panel members receive controlled feedback on the panel’s opinions. The consensus of opinions can then be combined and used to guide decision-making.

The “pure” or “basic” Delphi process involves an unstructured initial round, but this style would have been inefficient in terms of this research project as it can generate large amounts of minimally relevant responses. There are many modifications on the methodology of the “basic Delphi” technique, including what has been called the “reactive Delphi” which was the style employed in this work. The type of modifications employed depend on the needs of each individual study. The “reactive Delphi” asks expert panellists to give opinions on a previously prepared work, rather than creating lists of items.

The process for a “reactive Delphi” requires a number of steps: identifying the expert panel members; inviting suitable candidates to participate; circulating the original stimulus material to the expert panel; gauging opinions from the panellists; analysing the responses; adapting the material in accordance with the responses so that only items that meet the consensus threshold continue through to the next round of the process; re-circulating the amended material and repeating the process of gauging opinion from the panel; analysing their responses again and repeating the process for three iterative rounds; and finalising the material based on their opinions.
Expert panels generally recruit individuals who are perceived to have expertise in the subject under investigation\(^{147}\). It may be useful to include participants who are not only experts but also potential users of the finished material as they may have a ‘vested interest’ in seeing their opinions represented\(^{148}\) and so for this study experienced nurses and midwives were invited to participate as they would have a greater stake in the results. There is no set or standard sample size for a Delphi panel, the number of panellists required depends on the scope of the project and the time frame for data collection\(^ {147}\).

Regardless of the composition or background of the participants, all kinds of Delphi processes are dependent on continued commitment from participants and the end result rests on participants having the time to commit to the process and to maintain their involvement\(^ {146}\). Attrition from expert panels has been found to be a problem and this may lead to a degree of response bias\(^ {145}\). Poor response rates, particularly in final rounds, are common\(^ {144}\). One method employed to prevent ‘respondent fatigue’ and decrease attrition is to decrease the number of iterative rounds or fix it to between two and four\(^ {145}\).

While anonymous responses may be more frank and open, anonymity cannot be guaranteed in a Delphi process as while the panel members do not interact with each other and so are unaware of their identities, they do interact with the researcher\(^ {145, 147}\). Panellists’ anonymity from each may be sufficient to allow them to give opinions that are both truthful and useful\(^ {147}\).

Several limitations have been identified with the use of Delphi processes, the chief being that there can be difficulties in deciding who should be considered an "expert" for the purposes of the project\(^ {144}\). A further limitation that panel consensus does not equal fact; the findings of a Delphi process can only ever be expert opinion\(^ {147, 148}\). For questions of relevance, appropriateness or usefulness, there are few other methodologies that can as quickly and effectively access the opinions of potential users or beneficiaries provided the process is conducted with sufficient rigour\(^ {144, 145}\).

### 3.3.2 Research Design

The Delphi process was conducted with a panel of nurses and midwives in order to adapt the Beliefs About Aromatherapy Scale\(^ {48}\). This scale was originally devised for use with a sample of herbal medicine students and so, needed to be modified for use with nurses and midwives because of the difference in scope of practice, area of practice and educational background. The Delphi panel was asked to give their opinion on the relevance of each item on the tool both to
nursing and to the Australian healthcare system using a Likert-style rating scale (0 = not at all relevant, 4 = very relevant). Three iterative rounds were used with only items achieving 75% consensus continuing to the subsequent round. Panel members were able to suggest new items in round one.

This phase of the work was concluded in August, 2011. The results of the modified Delphi process are described in Chapter Five.

3.3.3 Participants

Population

The population for the Delphi process was senior registered nurses and midwives with significant experience in the nursing care of surgical patients. Potential participants were invited on the basis of their current work position (Nursing Grade 6 Clinical Nurse or Midwife or above). Names and email addresses were sourced from the hospital's telephone directory and an invitation email sent (Appendix A). Those staff who expressed an interest in participating were sent a participant information sheet which detailed the process of the study, after which they either confirmed their interest in participating, or declined in which case there was no further contact.

Sample

The sample size for the Delphi process was based on achieving a purposive sample of senior nurses and midwives with experience in postoperative care to form the Delphi panel. Given the number of clinical areas which provide postoperative care at the study hospitals (n = 21), a target of 12 participants was sought to provide an adequate and representative panel. Originally, 38 staff members were invited to take part in the study and of these 16 agreed and were entered into the process. For the first iterative round there were 11 returns; for round two, 9 forms were returned and for round three, 7 forms were returned.

A further expert panel comprised of myself, my research supervisor and a professor of natural medicine provided comment on the modified instrument and suggested additional items.

Inclusion criteria

Participants for the Delphi panel were invited from hospital clinical areas (surgical), nursing management, and nursing education. Registered nurses and midwives only were invited.
3.3.4 Instruments

The published version of the BAAS tool\textsuperscript{48} was used for the Delphi process. This tool comprises 19 items assessing participants’ beliefs about aromatherapy and was originally designed for use with students of herbal medicine. No information on the validity or reliability of this tool has been reported. Permission to adapt the tool was received from the original authors. The original survey tool is attached as Appendix B.

This tool was chosen as it was the only survey instrument able found following an extensive search of the literature, which had been designed specifically to measure beliefs about aromatherapy from a health practitioner viewpoint.

Participating panel members were emailed documents explaining the study process and the original BAAS tool with a Likert-style scale for them to indicate their opinions about the relevance of each item to nursing and/or midwifery practice (Appendix C).

Opinions on the existing BAAS tool items was collected through a series of iterative rounds. Rounds continued until consensus or stability was reached which in this case was achieved in three rounds\textsuperscript{145}. A 4-point scale (1 = not relevant, 4 = very relevant) was used for panel members to indicate their agreement with the relevance of the item to the domain and to the purpose of the tool overall. Consensus for the purposes of this study was set at 75% agreement on each item. Panel members had the opportunity to propose additional items in the initial round\textsuperscript{146}. After each round, the results for each item were tabulated in an Excel spreadsheet and the percentage of consensus calculated to ascertain which survey items should continue through to the next iterative round.

Following the Delphi process, an expert panel consisting of myself, my supervisor and a professor of natural medicine provided feedback and suggested additional items.

3.3.5 Analysis

Initial data analysis involved determining the level of agreement with the items in the BAAS to identify when the 75% level of consensus had been achieved. Panel responses for each round were collated in an Excel spreadsheet and percentage of agreement calculated. Those items for which at least 75% of the panel indicated a relevance rating of ‘relevent’ (3) or ‘very relevant’ (4) were retained in the tool to progress to the following round. Items with less than 75% agreement on their relevance were deleted from subsequent rounds.
3.4 SURVEY

3.4.1 Survey Methodology

The final part of this work involved testing the modified Nurses’ Beliefs About Aromatherapy (N-BAAS) survey tool among a population of registered nurses and midwives. Surveys, which are commonly used to investigate beliefs or test theories about behaviour, aim to systematically gather information from a group within a population in order to make statistical inferences about that population\textsuperscript{149}. While surveys are not considered to be “high level” research and they are prone to several risks of bias, particularly in a self-selected sample, they are an ideal way of investigating what people in a population actually believe or think\textsuperscript{150}.

A targeted anonymous survey such as the one in this study is a useful for investigating beliefs in a way that allows respondents to be open and truthful without fear of being judged or found “wrong”. In populations where internet access is difficult or uncommon, online surveys may not be an appropriate choice and hardcopy or paper surveys may attract a higher response rate\textsuperscript{151}.

3.4.2 Research Design

The modified N-BAAS tool was tested with group of registered nurses and registered midwives at the study hospitals. To reduce response bias, no identifying information was sought. The survey collected a small range of demographic data and the participants were instructed to indicate their level of agreement with the 15 statements on the N-BAAS tool (Appendix D).

3.4.3 Participants

Population

The population for the survey was registered nurses and midwives providing care to patients following surgery in the study hospitals (N = 1100). This group was considered to be the most suitable for inclusion as they were likely to be familiar with the standard treatments for PONV, and aware of the shortcomings of those treatments, such as adverse effects and lack of effect in some patients. Twenty different clinical areas were identified as providing postoperative care on a regular basis and so the surveys were distributed in these areas.

Sample

The sample size for the survey was based on the number of subjects required for factor analysis (at least 10 per item\textsuperscript{152}) and the likely return rate, based on a "worst-case scenario" of 15 or 20%, and the number of participants required to
enable factor analysis. The original BAAS tool has 19 items, but the Delphi and expert panel processes reduced this number to 15. Thus the minimum required sample size was 150; however the return rate of 26% from a participant pool of 1100 registered nurses and midwives gave a sample size of 285, which gave sufficient participants to enable the factor analysis.

Inclusion Criteria
All registered nurses and registered midwives at the study hospitals involved in caring for surgical patients were invited to participate. No exclusions were made on the basis of the participant’s type of employment (e.g., full-time, part-time, casual, temporary/agency).

Exclusion Criteria
Enrolled nurses, assistants in nursing, nursing students and clinical assistants/orderlies/wardspersons and/or any other persons not employed as registered nurses or midwives were excluded from this study as it is not in their scope of practice to plan and initiate nursing interventions independently. Medical staff were excluded as they were not the population of interest. Any surveys returned by participants indicating any of these as their position were discarded.

3.4.4 Instruments
Following completion of the Delphi process, the fifteen item Nurses’ Beliefs About Aromatherapy (N-BAAS) tool was formatted and a form constructed to record respondents’ demographic data items. The participant information sheets and the demographic data sheet were added to the survey tool to create the final instrument for distribution (Appendix E & F).

The scale modified by the Delphi process (the N-BAAS tool) was used to survey registered nurses and midwives to test the reliability and validity of the modified scale. Participants were asked to indicate their responses to the 15 items using a 7-point Likert scale (1 = very strongly disagree, 7 = very strongly agree). Demographic data was collected on age, gender, educational and professional qualifications, certification, current position, years of experience in current position, employment and practice setting, years of Registered Nurse/Registered Midwife (RN/RM) experience as well as current practice status and any complementary and alternative medicine qualifications held. The modified N-BAAS tool is in Appendix D.

The tool was administered as a hard-copy paper survey as it was felt that this would achieve a higher rate of return than an emailed or online survey as
experience within the study hospital had shown that nurses and midwives, particularly in clinical positions often do not check their email or have the opportunity to access computers for non-work-related tasks. The survey tool was disseminated to all clinical areas involved in the care of surgical patients at the study hospital. Specially labelled return boxes were also left in the staff common areas of each clinical area. The study and the purpose of the survey were discussed with the manager of each area or their representative before distribution of the surveys. Staff were invited to participate via advertising posters placed in each of the staff areas. The survey was closed for returns after four weeks when the collection boxes were retrieved from each participating area.

### 3.4.5 Data Analysis

Descriptive statistics were used to summarise sample characteristics and means and standard deviations for summarising the levels of nurses’ and midwives’ beliefs about aromatherapy. Means and standard deviations were calculated for the individual survey items as well as the summed total score. Factor analysis was undertaken to explore the factorial structure of the final N-BAAS tool. The cut-off for factors was an eigen value over 1 and factor loadings for items above 0.40 were retained. The relationships among the study variables of beliefs about aromatherapy, as well as demographic characteristics of age, education, work position, complementary and alternative medicine qualifications, and years of nursing experience were analysed using the independent samples t-test. Analysis was conducted to examine whether some nurses, according to their demographic characteristics, were more likely to have positive beliefs about aromatherapy. The level of significance was set at 0.05 and data analysed using SPSS version 15.

### 3.5 ETHICS AND LIMITATIONS FOR DELPHI PROCESS AND SURVEY

Due to the design of this work, ethical concerns centred chiefly on the need to preserve participant privacy and anonymity during the conduct of the Delphi process and the survey. Emails to the Delphi panel participants were sent using the BCC (Blind Carbon Copy) feature in the email program used, which allowed email to be sent to multiple recipients but prevented the email addresses from being seen. Emails to the Delphi panel were generically addressed to the group unless an individual query on the process was made by a panel member, in which case it was answered privately.
Anonymity was preserved during the survey by including an instruction in the Participant Information Sheet for respondents not to write their name or any other identifying data on the survey papers and by not including any demographic data items that could identify individual respondents. Completed surveys are stored in a locked filing cabinet.

Participants’ free choice to participate or not in the survey was supported by not identifying potential participants, and by not requiring or asking any individual to participate.

Ethical exemption was sought from the Mater Health Services Human Research Ethics Committee for conducting the systematic review and was granted on 22, January, 2008.

Approval for the two-part development of the N-BAAS tool was sought from Mater Health Services Human Research Ethics Committee and granted on 23 January, 2011, for the Delphi phase of the research and December 12, 2011 for the use of the amended N-BAAS tool in the survey phase (#1663A). (Appendix G & H)

Administrative ethics approval (#1100000420) was granted by Queensland University of Technology Research Ethics Committee on May 5, 2011. (Appendix I)

3.6 WORKPLACE HEALTH AND SAFETY

No health and safety implications outside the normal risks of office work were identified as being likely to occur during the conduct of this project. The Workplace Health and Safety policies of the study hospitals were adhered to at all times.
Chapter 4: Systematic Review

This chapter details the methods (section 4.3), findings (section 4.6) and conclusions (section 4.10) of a systematic review of the effectiveness of aromatherapy to treat postoperative nausea and vomiting. This systematic review was conducted under the auspices of the Cochrane Collaboration’s Anaesthesia Review Group, using the standard methods of the Cochrane Collaboration as detailed in section 4.1.2.

With the exception of section 4.1.2, the following text has been accepted for publication in the Cochrane Library of Systematic Reviews. Where section 4.11.1 indicates that more than one author was involved in completing that task (eg. risk of bias assessment), it is because Cochrane methods mandate the use of multiple reviewers to reduce the risk of bias in the conduct of the review, as previously discussed in section 4.1.2 below.

This Cochrane Review is published in the Cochrane Database of Systematic Reviews 2012, Issue 4. Cochrane Reviews are regularly updated as new evidence emerges and in response to feedback, and the Cochrane Database of Systematic Reviews should be consulted for the most recent version of the Review.


4.1 BACKGROUND

4.1.1 Aromatherapy and Postoperative Nausea and Vomiting

Aromatherapy has been recommended for the treatment of postoperative nausea and vomiting (PONV)\textsuperscript{34, 35}. It is known that this therapy is inexpensive, non-invasive, and generally has low levels of adverse effects\textsuperscript{11}, particularly in comparison to standard pharmacological treatments. What is not known is whether the clinical effectiveness justifies its use.

Nausea is an abdominal discomfort or queasiness that may be accompanied by vomiting (the forceful expulsion of stomach contents through the mouth).
Postoperative nausea and vomiting (PONV) is one of the most common adverse reactions to surgery and all types of anaesthesia, with 20% to 30% of all patients still suffering moderate to severe nausea and vomiting following general anaesthesia using volatile agents².

Aside from the distressing nature of PONV itself, as a result of PONV patients may experience such adverse effects as wound dehiscence, dehydration, electrolyte imbalances, or aspiration pneumonia². Other adverse effects may include increased patient bed days; unplanned readmissions (particularly in the case of day surgery)²; and decreased patient satisfaction³. Certain patients are more pre-disposed than others to suffering from PONV and risk factors include being female, a non-smoker, having a history of PONV, or perioperative opioid exposure¹. Along with postoperative pain, PONV is one of the main concerns of patients facing surgery and one of the main causes of patient dissatisfaction³.

Current treatment involves either the prophylactic or symptomatic administration of antiemetic drugs such as droperidol, metoclopramide, or 5-HT3 receptor antagonists such as ondansetron¹⁵³. Despite a wide range of available treatments, some patients will still experience PONV in varying levels of severity⁸. Clinically, the severity of PONV is generally measured by means of a visual analogue scale (VAS), which provides a visual representation of the patient's condition over a numerical range (for example 0 to 5), or verbal descriptive scales (for example no nausea, some nausea, very nauseated, retching, vomiting)⁷⁵. The effectiveness of the various drugs for PONV has already been the subject of a Cochrane review⁵¹; however no existing review has examined the effectiveness of aromatherapy to treat this condition.

The use of aromatherapy oils is recognized as an effective treatment for nausea of various aetiologies¹⁴, ⁴⁰, ⁸⁶, ¹⁵⁴. Aromatherapy uses the application of essential oils or other substances to any part of the body for the purposes of inhalation of the vapours or absorption of the oil into the skin, to treat or alleviate physical and emotional symptoms¹¹. Essential oils can be absorbed through the skin and may exert a physiological effect on cellular and organ function, although this is not clinically understood¹⁰². Aromatherapy is well accepted by many health consumers, who find it more pleasant and acceptable than the ingestion or injection of conventional drugs¹²⁴. A considerable number of health consumers already self-prescribe and administer aromatherapy products for various common conditions or consult qualified or unqualified aromatherapy practitioners for health advice¹²⁴.
In particular, ginger and peppermint, as either a topical application (massage or a compress) or via inhalation, are commonly recommended in the literature. The effectiveness of the oils may be due to analgesic and antiemetic properties (with peppermint oil and ginger oil) or anti-spasmodic properties (peppermint oil). Peppermint oil is well recognized for its role in digestive disorders, due principally to the presence of the menthols. Peppermint oil (Mentha piperita) is one of the oldest European herbs used for medicinal purposes. It is a hybrid species of spearmint (Mentha spicata) and water mint (Mentha aquatica). The essential oil is derived by steam distillation of the fresh aerial parts of the flowering plant. Peppermint oil is listed in the European Pharmacopeia, British Pharmacopoeia, and United States Pharmacopeia. The active ingredients of the peppermint essential oil (0.4% to 5%) are menthol (35% to 45%) and menthone (10% to 30%).

One possible mechanism of action of peppermint oil in the gastrointestinal system is inhibition of muscular contractions induced by serotonin and substance P. Early studies (1969) showed that direct administration of peppermint oil to the stomach (27 patients) caused relaxation of the lower oesophageal sphincter. Subsequent studies have shown that administration (dose of 0.1 ml peppermint oil in 20 ml of saline) to the sigmoid colon produced increased intraluminal pressure, abdominal cramps, and the urge to defecate and urinate, suggesting widespread stimulation of smooth muscle. In another study, peppermint oil injected into the colon (20 patients) was shown to relieve colon spasms. These apparently conflicting findings have yet to be explained by the research.

Peppermint oil has also been shown to accelerate the gastric emptying rate in dyspeptic patients as well as reduce the pain intensity. In a double-blind study, it was shown that the incidence of postoperative nausea in 18 gynaecological patients was significantly reduced in those that inhaled the peppermint oil vapours. In another randomised double blind study, a liquid herbal extract containing peppermint oil as the principal ingredient was found to relieve the symptoms of pain, nausea, belching, and heartburn.

There have been a number of studies conducted using ginger oil with conflicting results. Isopropyl alcohol is said to be a traditional nausea remedy from South America but none of the papers citing this provide a primary source for this information. Isopropyl alcohol, also known as rubbing alcohol and commonly found in the type of 'prep-pad' used to clean skin prior to injection,
does appear to be widely used in some post-anaesthesia care units to treat PONV\textsuperscript{17-19, 40, 50, 122} and is the subject of several effectiveness studies.

**4.1.2 Cochrane Review Methodology**

The systematic review is central to evidence-based practice\textsuperscript{163}. More comprehensive than the results of a single research study or literature review; systematic reviews collate, evaluate, extract, and analyse all the research data about a research question and present an unbiased finding\textsuperscript{164}. Systematic reviews begin with a "clearly formulated question, and then use systematic and explicit methods to identify, select and critically appraise relevant research and to collect and analyse data from the studies included in the review"\textsuperscript{165}(p.389). The strength of the Cochrane review methodology is, at least in part, due to its focus on standardised methods, which are continually tested and made more rigorous\textsuperscript{166}. The standardisation of methods in Cochrane reviews is further assisted through the provision of the Review Manager software program, which provides both a template for the reporting of the systematic review and functions for the meta-analysis of data\textsuperscript{167}.

The methods of a systematic review are designed to reduce the risk of bias\textsuperscript{59}. Transparency is mandated in the process. All Cochrane reviews must first publish a protocol, or plan, of the proposed review detailing the planned review question, the planned search methods for studies, the objectives, inclusion and exclusion criteria in terms of research designs, participants, interventions and outcomes, and planned data analysis, all of which must pass through a peer review process prior to publication\textsuperscript{59}. The publication of systematic review protocols is important as it allows for public scrutiny of the proposed review and prevents review methods being changed during the conduct of the review, which could lead to an increased risk of bias in the review’s findings. Any differences between the protocol and the published review must be identified and explained in the final publication\textsuperscript{59}. As with an experimental trial, transparent reporting of the systematic review’s methods aims to allow a person other than the authors to reproduce the process and achieve similar results.

Reduction of the risk of bias is important within the methods of the review. Each included study is evaluated for internal validity by the use of the Risk of Bias Tool, a recent change to the Cochrane methods which changes the focus from the previous requirement to perform a ‘quality assessment’ which did not have the same focus on internal study validity\textsuperscript{166}. The risk of bias assessment process addresses five essential fields of potential bias in research studies: selection bias, performance bias, detection bias, attrition bias, and reporting bias\textsuperscript{59}. 
Selection bias risk is assessed through examination of the methods of randomisation and concealment allocation; performance bias through examination of the blinding of participants and trial staff; detection bias through examining the blinding of outcome assessors; attrition bias through assessment of incomplete data reporting; and reporting bias through investigation of unreported outcome data\textsuperscript{166}. Risk of bias is reported as being ‘low risk’, ‘unclear risk’, or ‘high risk’ and systematic review authors are expected to use quotations from the study to support their findings\textsuperscript{59}.

The risk of biased findings in a systematic review is further reduced by the requirement for authors to seek out and include, wherever appropriate, unpublished studies. Published literature has been found to both overestimate the efficacy and underestimate the harms of interventions\textsuperscript{168}. Studies showing significant effects are more likely to reach publication, than those showing no effects or negative effects, which may lead to publication bias\textsuperscript{169}. Unpublished studies may be identified from conference proceedings, trial registries, or other grey literature resources such as government databases\textsuperscript{168}.

Lastly, peer review is an ongoing process over the life of a Cochrane review. Systematic reviews are subject to internal examination (within the Cochrane Review Group) at the title registration stage, to external peer review at the protocol registration stage and again when the completed systematic review is submitted for publication. This process involves peer reviewers who are subject area specialists, methodology specialists, as well as consumer representatives\textsuperscript{59}.

The result of this process should be that the findings of a Cochrane systematic review are transparent, reproducible and completely defensible.

### 4.2 OBJECTIVES

- To establish what effect the use of aromatherapy has on the severity of established postoperative nausea and vomiting
- To establish what effect the use of aromatherapy has on the duration of established postoperative nausea and vomiting
- To establish whether aromatherapy can be used with safety and clinical effectiveness comparable to standard pharmacological treatments to treat established postoperative nausea and vomiting
4.3 METHODS

4.3.1 Criteria for Considering Studies for This Review

Types of Studies
We considered any randomised controlled trials (RCTs) or controlled clinical trials (CCTs) that evaluated the effect of aromatherapy on established PONV. In order to obtain the widest range of studies we set no date of publication or language limits.

Types of Participants
We considered all studies that included patients (both adult and paediatric, paediatric being children aged less than 18 years of age) having any type of surgical procedure under general anaesthesia, regional anaesthesia, or sedation, either as hospital inpatients or in day or ambulatory facilities, who were given aromatherapy treatments for management of existing PONV. For the purposes of this review we considered postoperative to be the period from day of surgery to discharge from hospital or, in the case of day hospital patients, up to the fifth post-discharge day.

We excluded studies of nonsurgical patients (medical, oncology). We also excluded studies in which aromatherapy was used solely to prevent postoperative nausea and vomiting.

Types of Interventions
Interventions of interest were those where aromatherapy products were used by any delivery method (for example direct inhalation, diffusion, massage or compress) to treat symptoms of established postoperative nausea and vomiting, either in comparison to a placebo or in comparison to standard antiemetic treatments. Aromatherapy was defined as the inhalation of the vapours of any substance for the purposes of a therapeutic benefit.

Types of Outcome Measures

Primary Outcomes
- Severity of nausea or vomiting, or both, post-initiation of treatment; measured by a validated scale or medical or nursing observation
- Duration of nausea or vomiting, or both, post-initiation of treatment; measured by patient report or medical or nursing observation

Secondary Outcomes
- Use of pharmacological antiemetics
Any adverse reactions or events (common reactions to aromatherapy include skin rashes, dyspnoea, headache, cardiac arrhythmias, hypotension, hypertension, or dizziness11)

Patient satisfaction with treatment as measured by a validated scale

4.4 SEARCH METHODS FOR IDENTIFICATION OF STUDIES

4.4.1 Electronic Searches

We searched the Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library 2011 Issue 3); MEDLINE (via Ovid) (1966 to August 2nd, 2011); EMBASE (1966 to 2 August 2011); CINAHL (EBSCO Host 1982 to 2 August 2011); CAM on PubMed (1966 to 2 August 2011); Meditext (1995 to 2 August 2011); LILACS database (1982 to 2 August 2011); ISI Web of Science (1985 to 2 August 2011).

We developed a specific strategy for each database. We based each search strategy on that developed for MEDLINE (see Appendix J for details of all search strategies). We combined the MEDLINE search strategy with the Cochrane highly sensitive search strategy, phases one and two, as contained in the Cochrane Handbook for Reviews of Interventions59.

4.4.2 Searching Other Resources

We also identified trials by manually searching abstracts of relevant conference proceedings such as the National Association for Holistic Aromatherapy Conference.

We checked the reference lists of relevant articles and attempted to contact relevant trial authors to identify any additional or ongoing studies.

We also searched for relevant trials in specific sites:

Current Controlled Trials at http://www.controlled-trials.com;

Clinical Study Results at http://www.clinicalstudyresults.org;

SIGLE at http://opensigle.inist.fr/ (grey literature);


We did not apply language or publication date restrictions.

4.5 DATA COLLECTION AND ANALYSIS

4.5.1 Selection of Studies
Two authors (SH and ES) independently scanned the titles and abstracts of reports identified by the described variety of search strategies.

We retrieved and evaluated potentially relevant studies, chosen by at least one author, in full-text versions. We retrieved and translated any articles which appeared relevant but were not published in full in English. Translations were conducted by native speakers of the required languages who were either health professionals or professional translators.

Two authors (SH and ES) independently assessed the congruence of trials with the review's inclusion criteria using a checklist that was designed in advance for that purpose (Appendix K).

The third author (AC) settled any disagreements.

4.5.2 Data Extraction and Management
Two authors (SH and ES) independently extracted data using a tool developed and piloted by the authors (Appendix L). We resolved any disagreements through consultation with the third author (AC).

4.5.3 Assessment of Risk of Bias in Included Studies
We assessed the risk of bias using the tool provided in the RevMan 5.1 software, based on the work of The Cochrane Collaboration and Higgins (2011)59. Any disagreements were adjudicated by the third author (AC). We used the following five criteria to assess risk of bias for each individual study: random sequence generation, allocation concealment, blinding, incomplete outcome data, and selective reporting.

4.5.4 Measures of Treatment Effect
Because of the subjective nature of nausea, measures of treatment effect were largely limited to patient-reported effects, measured by various scales including visual analogue scales (VAS), verbal numerical rating scales (VRNS) and descriptive ordinal scales (DOS). We included other measures of effect, such as number of vomiting episodes or retching, and the use of pharmacological 'rescue' antiemetics. All outcome measures that were evaluated were
dichotomous and, as such, we used relative risk (RR) with 95% confidence interval (95% CI) to measure treatment effect.

4.5.5 Unit of Analysis Issues
For cross-over trials, a paired t-test was to be used to analyse participant data if sufficient data had been available. Had cluster randomised trials been included, effect estimates and standard errors would have been meta-analysed using the generic inverse-variance method in RevMan.

4.5.6 Dealing with Missing Data
Where necessary, we contacted authors of included studies regarding missing study information. We were able to contact some authors to retrieve missing data, such as details about randomisation and statistical detail, and standard deviations; however others did not reply or were not contactable. Where data were found to be missing and the authors were not contactable we, where possible, calculated missing statistics (such as standard deviations) from other quoted statistics (such as standard error or CIs). If missing data remained then we performed an available case analysis, excluding data where outcome information was unavailable.

4.5.7 Assessment of Heterogeneity
We assessed statistical heterogeneity through the use of the Chi² test, as well as reviewing the I² statistic. If either the Chi² test resulted in a P-value less than 0.10 or the I² statistic was greater than 40%, further investigation of the reason for heterogeneity was carried out. Clinically diverse studies were analysed separately.

4.5.8 Assessment of Reporting Biases
Due to the small number of studies included in this review, and the small number able to be included in the meta-analyses, we considered it inappropriate to generate funnel plots to assess reporting biases. We did consider studies from a wide range of locations, languages and publications, which we believe has reduced the likelihood of reporting biases affecting our findings.

4.5.9 Data Synthesis
We entered all trials included in the systematic review into Review Manager (RevMan 5.1) and combined data quantitatively where possible. We have presented the main outcomes in this review as dichotomous variables. We calculated pooled estimates using the fixed-effect model with the Mantel-
Haenszel method as the studies were homogenous and small numbers of events were observed. We used a random-effects model when the $I^2$ statistic was more than 50%.

### 4.5.10 Subgroup Analysis and Investigation of Heterogeneity

Subgroup analyses were conducted where data were available, as described by Deeks et al.\textsuperscript{171} and as recommended in Section 8.8 of the *Cochrane Handbook for Systematic Reviews of Interventions*\textsuperscript{59}. We planned to compare:

- adults and children;
- different types of surgery (e.g. orthopaedic and gynaecologic surgery);
- types of aromatherapy delivery methods (e.g. inhalation, massage, ingestion);
- trial quality (e.g. RCT and CCT).

Due to the limited data available, we were unable to perform any subgroup analyses.

### 4.5.11 Sensitivity Analysis

Due to considerable concern about the risk of bias because of probable confounding in Merritt (2002)\textsuperscript{40} we performed a sensitivity analysis and have reported findings both with and without the results of this study.

### 4.6 RESULTS

#### 4.6.1 Description of Studies

The studies were randomised controlled trials (RCTs) or controlled clinical trials (CCTs) conducted on postoperative adult and paediatric patients in post-anaesthesia care units (PACU) and same-day surgery units (SDSU). The intervention groups were given aromatherapy treatments to treat complaints of postoperative nausea and vomiting. The control groups were treated with either a saline placebo or standard antiemetic drugs.

#### 4.6.2 Results of the Search

We conducted searches in a wide range of databases and sources: MEDLINE; CAM on PubMed; CENTRAL; EMBASE; CINAHL; Meditext; LILACS; Web of Science; Current Controlled Trials; Clinical Study Results; SIGLE; New York Library of Medicine Grey Literature Report; National Institute of Clinical Studies; Google Scholar (English, German, Spanish); Science.gov (grey literature);
Conference Proceedings of the National Association for Holistic Aromatherapy; and reference lists.

Of the 1386 articles we identified, 44 were deemed relevant enough to be retrieved for further evaluation. After appraisal of the full version of each study, nine studies were found to meet the criteria for inclusion in the review. For further details see Figure 4.1.

Figure 4.1. Searching Flowchart
4.6.3 Included Studies

We included nine studies, comprised of six RCTs16-19, 122, 162 and three CCTs14, 39, 40 with a total of 402 participants. Age data for all participants were not available for all studies. See the table of Characteristics of Included Studies in Appendix M for further details.

4.6.4 Excluded Studies

We excluded 35 studies for not meeting the inclusion criteria, either by study design (not RCT or CCT), or by study outcomes (prevention of PONV not treatment). See the Characteristics of Excluded Studies in Appendix N for details.

4.7 RISK OF BIAS IN INCLUDED STUDIES

We assessed the risk of bias in terms of allocation sequence generation, blinding, incomplete reporting of outcome data, and selective reporting. Risk of bias was found to be moderate to high across all included studies. For details of the risk of bias assessment, see Figure 4.2 and Figure 4.3.

Figure 4.2

Methodological quality graph: review authors' judgements about each methodological quality item presented as percentages across all included studies.
Figure 4.3

Methodological quality summary: review authors’ judgements about each methodological quality item for each included study.

4.7.1 Allocation (selection bias)

Methods of allocation varied across the included studies. In four studies, the method of randomisation was explicitly stated: Wang\textsuperscript{122} utilised a 'random number table'; Cotton\textsuperscript{17} and Pellegrini\textsuperscript{19} utilised a 'computer generated random numbers table'; and Anderson\textsuperscript{162} used a 'random number generator'. For Kamalipour\textsuperscript{16} the treatment and control groups were "randomly selected" but the authors did not state what method of randomisation was used. Similarly, in Winston\textsuperscript{18} participants were "randomly assigned" to receive either the treatment or control but the method of sequence generation was not stated. In Langevin\textsuperscript{39}, which used a cross-over clinical trial design, the test agents were administered in
a "random sequence" but again the method of randomisation was not stated. The study by Merritt was a controlled clinical trial and participants were not randomly allocated, rather assignment to the treatment and control groups was alternated by day. The participants in Tate were "randomly allocated" to wards which had been assigned to the separate treatment, the control and placebo arms of the study.

Allocation concealment appeared to have been undertaken for four studies. The remaining five studies reported no data on whether allocation was concealed.

### 4.7.2 Blinding (performance bias and detection bias)

Five included studies appeared to have undertaken at least some blinding of participants and assessors, published details were unclear for two, and for two studies blinding was explicitly not done. Three included studies explicitly blinded assessors.

### 4.7.3 Incomplete Outcome Data (attrition bias)

Data appeared to have been reported for all participants and outcomes in seven studies but it was unclear whether this had occurred in the remaining two studies.

### 4.7.4 Selective Reporting (reporting bias)

For seven studies it was unclear whether there was any degree of selective reporting, and for two studies it appeared a degree of selective reporting had taken place.

### 4.7.5 Other Potential Sources of Bias

Other potential sources of bias were evident in two studies. Due to the design of the study by Tate, it was possible there was some demand characteristic effect (an effect where participants interpret the purpose of the study and modify their behaviour or reporting accordingly) on patient self-reporting of results. The authors of Merritt reported that their study was probably confounded by the aggressive preoperative antiemetic prophylaxis given to 104 out of the 111 participants enrolled into the study. Four studies appeared free of other potential sources of bias. It was unclear from the minimal data reported in Langevin and Kamalipour whether there were any other potential sources of bias.
4.8 EFFECTS OF INTERVENTIONS

Eight studies examined the effectiveness of isopropyl alcohol (IPA) as an antiemetic and two studies investigated the effectiveness of peppermint oil (one study trialled both interventions). All included studies measured nausea as a chief outcome. Five studies also reported data on the number of participants requiring rescue antiemetics for unresolved nausea. All meta-analyses resulted in both significance values for heterogeneity testing of greater than 0.10 and $I^2$ values less than 40%, indicating that statistical heterogeneity was not present.

4.8.1 Primary Outcome: Severity and Duration of Nausea

The only studies able to be compared for this outcome, with compatible drug administration times, were the Langevin and Kamalipour studies. The primary outcome analysis was not able to be performed on these two studies as the only measure of nausea for the Kamalipour study was percentage of patients who responded to the treatment, and this measure could not be compared with the Langevin study as there was ambiguity in the paper's definition of response.

The Anderson study could not be compared with the Langevin and Kamalipour studies for this outcome as the times for drug administration were: on first report of nausea, two minutes later, then three minutes later; which is different to the drug administration times for the two other studies.

The two studies examining IPA versus standard drug treatment were also not able to be compared as the number of applications of IPA differed between the studies. For the Cotton study, the maximum number of IPA applications was three whereas for the Winston study the maximum number of IPA applications was two.

Finally, the two studies which looked at peppermint aromatherapy were also not able to be compared due to differing drug administration times and units of measurement.

The single paediatric study able to be included compared isopropyl alcohol (IPA) and saline in a population of 39 children having elective outpatient surgery under general anaesthesia. This study found that while IPA did have an effect on postoperative nausea at 20 minutes post-treatment ($P = 0.05$), this effect could not be sustained at 60 minutes ($RR = 2.85$, 95% CI 0.32 to 25.07, $P = 0.35$). No effect on postoperative vomiting was able to be demonstrated at 20 minutes or 60 minutes ($RR = 1.27$, 95% CI 0.33 to 4.93).
4.8.2 Primary Outcome: Duration of Nausea

Findings for studies measuring time to relief of nausea, which could not be combined statistically, are presented in Table 4.1.

Table 4.1. Studies measuring time to relief of nausea

<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Intervention/Control</th>
<th>Outcome</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cotton 2007</td>
<td>RCT</td>
<td>IPA/ondansetron</td>
<td>Time to 50% reduction in nausea (VNRS(^1))</td>
<td>IPA: mean 15.00 (SD: 10.6mins) Ondansetron: mean 33.88 (SD: 23.2mins)</td>
</tr>
<tr>
<td>Kamalipour 2002</td>
<td>RCT</td>
<td>IPA/saline</td>
<td>Percentage &quot;response(^2) to treatment within 5 minutes</td>
<td>IPA: 78% Saline: 7.3%</td>
</tr>
<tr>
<td>Langevin 1997</td>
<td>CCT</td>
<td>IPA/saline</td>
<td>Percentage with complete relief of nausea in 5 minutes</td>
<td>IPA: 80% Saline: 0%</td>
</tr>
<tr>
<td>Pellegrini 2009</td>
<td>RCT</td>
<td>IPA/Promethazine</td>
<td>Mean time to 50% reduction in nausea scores (VNRS(^1))</td>
<td>IPA: (mean +/- SD) PACU(^3): 6.43 +/- 3.78 minutes SDSU(^4): 8.33 +/- 4.82 minutes HOME(^5): 16.58 +/- 6.9 minutes Promethazine: (mean +/- SD) PACU(^3): 20.5 +/- 18.236 minutes SDSU(^4): 23.3 +/- 18.86 minutes HOME(^5): 26.67 +/- 12.5 minutes</td>
</tr>
<tr>
<td>Winston 2003</td>
<td>RCT</td>
<td>IPA/ondansetron</td>
<td>Mean time to 50% reduction of VNRS(^1)</td>
<td>IPA: 6.3 minutes Ondansetron: 27.7 minutes</td>
</tr>
</tbody>
</table>

Footnotes

\(^1\)VRNS: Verbal Numeric Rating Scale

\(^2\)Meaning of response not defined by study authors.

\(^3\)PACU: Post-Anaesthesia Care Unit

\(^4\)SDSU: Same Day Surgery Unit

\(^5\)Home: Participant’s residence post-discharge
4.8.3 Primary Outcome: Severity of Nausea

Studies measuring severity of nausea by nausea scale measurements, which could not be combined statistically, are presented in Table 4.2.

Table 4.2. Studies measuring a decrease in nausea scores

<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Intervention/Control</th>
<th>Outcome</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Merritt 2002</td>
<td>CCT</td>
<td>IPA/standard antiemetics</td>
<td>Decrease in mean nausea score (DOS(^1)) 0-10 (0 = no nausea, 10 = worst nausea and vomiting imaginable)</td>
<td>IPA: Mean DOS(^1) score Pre-treatment: 5.71 Post-treatment: 2.7 Standard treatment: Pre-treatment: 6.11 Post-treatment: 1.94</td>
</tr>
<tr>
<td>Tate 1997</td>
<td>CCT</td>
<td>Peppermint oil/peppermint essence/standard treatment</td>
<td>Mean daily nausea scores (DOS(^1)) 0-4 (0 = no nausea, 4 = about to vomit)</td>
<td>Standard treatment: mean daily nausea score = 0.975 Peppermint essence mean daily nausea score (placebo): 1.61 Peppermint oil mean daily nausea score: 0.5</td>
</tr>
<tr>
<td>Wang 1999</td>
<td>RCT</td>
<td>IPA/saline</td>
<td>Percentage of participants with decrease in nausea after 3 treatments (VAS) 0-100 (0 = no nausea, 100 = extreme nausea)</td>
<td>IPA: 91% Saline: 40%</td>
</tr>
</tbody>
</table>

Footnotes

\(^1\)DOS: Descriptive Ordinal Scale

4.8.4 Secondary Outcome: Use of Rescue Antiemetics

Four studies with a total of 215 participants compared isopropyl alcohol to standard treatment (ondansetron or promethazine) and reported the number of participants in each group who required rescue antiemetics. The studies by Cotton\(^17\), Merritt\(^40\), Pellegrini\(^19\) and Winston\(^18\) were able to be combined in a meta-analysis which showed a statistically significant effect (RR 0.66, 95% CI 0.45 to 0.98, \(P = 0.04\)) (Figure 4.4). These findings are summarised in Summary of Findings 1 (Table 4.3).
Figure 4.4. Analysis 1: Isopropyl alcohol versus standard treatment for use of rescue antiemetics.

Due to the likely confounding of the study by Merritt\(^40\) from the administration of preoperative prophylactic antiemetics to 94 out of the 111 original participants, a sensitivity analysis was performed. Without the Merritt data there was no statistically significant evidence of an effect (RR 0.66, 95% CI 0.39 to 1.13, \(P = 0.13\)) (Figure 4.5).

Figure 4.5. Analysis 2: Isopropyl alcohol versus standard treatment for use of rescue antiemetics (sensitivity analysis).
Table 4.3. Summary of Findings 1

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Illustrative comparative risks* (95% CI)</th>
<th>Relative effect (95% CI)</th>
<th>No of Participants (studies)</th>
<th>Quality of the evidence (GRADE)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Requirement for rescue antiemetics</td>
<td></td>
<td><strong>259 per 1000</strong> (176 to 384)</td>
<td><strong>RR 0.66</strong> (0.45 to 0.98)</td>
<td>215 (4 studies)</td>
<td><strong>low</strong>¹,²</td>
</tr>
<tr>
<td>Adverse effects</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>See comment</td>
<td>See comment</td>
<td>Not estimable</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*The basis for the assumed risk (e.g. the median control group risk across studies) is provided in footnotes. The corresponding risk (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

CI: Confidence interval; RR: Risk ratio;
GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

Separating out results for participants with nausea only, as reported in Cotton¹⁷; Winston¹⁸ and Pellegrini¹⁹, we found that the proportion requiring rescue antiemetics was not significantly different between the experimental and control groups (RR 0.66, 95% CI 0.39 to 1.13, P = 0.13) (Figure 4.6).
Figure 4.6. Analysis 3: Isopropyl alcohol versus standard treatment for use of rescue antiemetics in postoperative nausea only.

Three studies of adult patients\textsuperscript{16, 39, 162} with a total of 135 participants compared isopropyl alcohol and saline and measured the number of participants who required rescue antiemetics. They were able to be combined. Meta-analysis trends toward evidence of an effect (RR 0.30 95% CI 0.09 to 1.00, $P = 0.05$) (Analysis 4).

Figure 4.7. Analysis 4: Isopropyl alcohol versus saline for use of rescue antiemetics.

These findings are summarized in table 4.4.
### Table 4.4 Summary of Findings Table 2.

**Isopropyl alcohol compared to saline for treatment of postoperative nausea and vomiting**

**Patient or population:** patients with treatment of postoperative nausea and vomiting  
**Settings:** Post-anaesthesia Care Units  
**Intervention:** Isopropyl alcohol  
**Comparison:** saline

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Illustrative comparative risks* (95% CI)</th>
<th>Relative effect (95% CI)</th>
<th>No of Participants (studies)</th>
<th>Quality of the evidence (GRADE)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Assumed risk</td>
<td>Corresponding risk</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>saline</td>
<td>Isopropyl alcohol</td>
<td>868 per 1000</td>
<td><strong>200 per 1000</strong> (122 to 330)</td>
<td>RR <strong>0.30</strong> (0.09 to 1.00)</td>
<td>135 (3 studies)</td>
</tr>
</tbody>
</table>

**Requirement for rescue antiemetics**<sup>1,2</sup> count

<table>
<thead>
<tr>
<th>Adverse effects</th>
<th>See comment</th>
<th>See comment</th>
<th>Not estimable</th>
<th>0 (0)</th>
<th>See comment</th>
<th>No data on this outcome</th>
</tr>
</thead>
</table>

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

**CI:** Confidence interval; **RR:** Risk ratio;

**GRADE Working Group grades of evidence**

**High quality:** Further research is very unlikely to change our confidence in the estimate of effect.

**Moderate quality:** Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

**Low quality:** Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

**Very low quality:** We are very uncertain about the estimate.

---

**Footnotes**

1. Participants enrolled into study on complaint of nausea and/or vomiting.
2. Calculated using control group results.
3. Study by Langevin 1997 is controlled clinical trial and not randomised.
4. Total number of events is less than 300.

---

One study of 39 paediatric patients having day surgical procedures<sup>122</sup> also compared isopropyl alcohol and saline and measured the number of participants...
requiring rescue antiemetics. For participants with nausea only, 60% of those in the placebo (saline) group required rescue antiemetics compared to 9% of those in the IPA group (RR 0.15, 95% CI 0.02 to 1.05). For participants with vomiting, 89% of the saline group required rescue antiemetics compared to 67% of the IPA group (RR 0.75, 95% CI 0.23 to 1.12).

One RCT\textsuperscript{162} trialled a comparison of IPA, peppermint oil and saline insufflations. This study randomised 33 participants to receive either, IPA, peppermint oil or saline to treat reported nausea in a postoperative care unit. Of the participants receiving IPA, 45% required rescue antiemetics, while 60% of participants in the peppermint oil group and 50% of the control (saline) group required rescue antiemetics. This study found no significant difference between the treatment and control groups (no significance value reported).

### 4.8.5 Secondary Outcome: Adverse Reactions

No data on adverse reactions to the experimental substances were reported by any of the included studies.

### 4.8.6 Secondary Outcome: Patient Satisfaction with Treatment

Four studies measured patient satisfaction with treatment. Cotton\textsuperscript{17} (comparing IPA to ondansetron) used a four-point ordinal scale in which the participants were asked to rate their postoperative experience as poor, fair, good or excellent. Participants in both the treatment and control groups in this study reported their experience as good or excellent, resulting in no statistically significant difference between the groups ($P > 0.05$).

Winston\textsuperscript{18} also measured patient satisfaction using a four-point ordinal scale ($0 =$ poor; $1 =$ fair; $2 =$ good and $3 =$ excellent). For the ondansetron group: $0 = 1$ participant (3%); $1 = 2$ participants (6%); $2 = 17$ participants (52%); and $3 = 13$ participants (39%). For the IPA group, the satisfaction numbers were: $0 = 0$ participants; $1 = 0$ participants; $2 = 18$ participants (47%), and $3 = 20$ participants (53%). The authors stated that although these findings were not statistically significant, they nonetheless regarded them as clinically significant (unreported data supplied via email). Results from Cotton\textsuperscript{17} and Winston\textsuperscript{18} were collapsed into binary data (good or excellent interpreted as satisfied) and combined in Analysis 5.
Figure 4.8. Analysis 5: Aromatherapy versus standard treatment for patient satisfaction.

Patients also reported high levels of satisfaction with their treatment regardless of allocation in Pellegrini\textsuperscript{19}, with a median score of 4 on a 5-point ordinal scale (1, totally dissatisfied; 2, somewhat dissatisfied; 3, somewhat satisfied; 4, satisfied; 5, totally satisfied).

Anderson\textsuperscript{162} measured patient satisfaction on a VAS (0 mm extremely dissatisfied, 100 mm fully satisfied). Participants across all three groups reported high levels of satisfaction with their treatment: IPA 90.3 (SD 14.9); peppermint 86.3 (SD 32.3); saline 83.7 (SD 25.6).

The results from all studies reporting on this outcome are collated in Table 4.5.

Table 4.5. Patient satisfaction with treatment

<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Intervention/Comparison</th>
<th>Measure</th>
<th>Satisfied</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cotton</td>
<td>CCT</td>
<td>IPA/ondansetron</td>
<td>4-point DOS (poor, fair, good, excellent)</td>
<td>Good or excellent: Intervention: 38/38 Comparison: 34/34</td>
</tr>
<tr>
<td>Winston</td>
<td>RCT</td>
<td>IPA/ondansetron</td>
<td>4-point DOS (poor, fair, good, excellent)</td>
<td>Good or excellent: Intervention: 38/50 Comparison: 30/50</td>
</tr>
<tr>
<td>Pellegrini</td>
<td>RCT</td>
<td>IPA/Promethazine</td>
<td>5-point DOS (1 = totally unsatisfied, 5 = totally satisfied)</td>
<td>Both groups report median score 4</td>
</tr>
<tr>
<td>Anderson</td>
<td>CCT</td>
<td>IPA/Saline/Peppermint</td>
<td>100mm VAS (0 mm extremely dissatisfied; 100 mm fully satisfied)</td>
<td>IPA: 90.3 (SD: 14.9) peppermint: 86.3 (SD: 32.3) saline: 83.7 (SD: 25.6)</td>
</tr>
</tbody>
</table>
4.9 DISCUSSION

4.9.1 Summary of Main Results

This review was able to include studies of isopropyl alcohol and peppermint oil aromatherapy compared to a saline placebo, ondansetron, promethazine, or other unspecified 'standard antiemetic' treatments. All aromatherapy was delivered via direct inhalation. There were 311 adult and 91 paediatric patients in the included studies. The majority of patients were women. Studies were conducted in both inpatient and day surgery settings. Outcomes measured were time to reduction in nausea, severity of nausea, number of nausea and vomiting events, the use of 'rescue' antiemetics, patient satisfaction, recurrence of symptoms, and cost of treatment.

Isopropyl alcohol (IPA) has been tested in several studies, both against standard pharmacological treatments and against other aromatherapies and placebo, in both adults and children. In comparison to saline placebo, IPA appears effective in reducing the number of patients requiring rescue antiemetics\textsuperscript{16, 39} and in providing short-term relief of symptoms in children\textsuperscript{122}. In two studies\textsuperscript{17, 18} IPA provided faster time to 50\% relief of symptoms than ondansetron and promethazine\textsuperscript{19}; however when meta-analysed there was no statistically significant difference in the number of participants requiring rescue antiemetics in the combined results of these three studies.

Peppermint oil insufflations are often recommended for PONV\textsuperscript{11, 154, 173} but this review was unable to find sufficient evidence to support this. Two studies examined the use of peppermint as a treatment for PONV\textsuperscript{14, 162}, of which only Anderson\textsuperscript{162} was adequately randomised and blinded. Tate\textsuperscript{14} reports evidence of an effect, but methodological concerns mean that these results should be viewed with caution. Anderson\textsuperscript{162} found that the effect of peppermint oil insufflation was not statistically different from the effect of insufflations of isopropyl alcohol or saline.

No adverse reactions were reported by any of the included studies.

Patient satisfaction with aromatherapy treatment appeared high in studies that measured this outcome\textsuperscript{17-19, 162}, with patients reporting high levels of satisfaction with their experience. It should be noted that all participants (treatment and comparison groups) in these studies reported high levels of satisfaction.
4.9.2 Overall Completeness and Applicability of Evidence

It seems likely that further studies of isopropyl alcohol to treat postoperative nausea and vomiting could provide different results from those described here. Well-conducted studies of peppermint oil or other aromatherapies may provide definitive evidence for the effectiveness of these therapies. The evidence base for aromatherapy to treat PONV is currently incomplete, with only one study of children meeting the inclusion criteria and many aromatherapy treatments incompletely investigated or tested. While there appears to be no evidence of adverse reactions from the use of the included interventions, it is unclear from the included studies whether data were collected on any possible adverse reactions experienced by participants. In the context of current postoperative practice, there is a place for adjunct therapies to treat PONV and while isopropyl alcohol vapour inhalation is a simple and inexpensive treatment that seems to be more effective than placebo, there is currently no evidence to suggest that it can replace pharmacological antiemetics.

Of additional concern are the early time points utilised by all included studies except Tate14, which did measure at 24 and 48 hours but only reported average daily scores for each group. Apfel et al.76 recommend that study authors measure PONV for early (greater than two hours) and late (to 24 hours) outcomes. The data able to be included in this review are incomplete for effects longer than 60 minutes.

Due to the many risk factors for and influences on PONV, such as type of anaesthesia, narcotic medication intake, sex, and type of surgery, it was a concern that there were differences between groups that might account for some of the effect. Examination of the demographic and procedural data shows that control and experimental groups were very similar and that confounding due to risk factors was unlikely.

It should be remembered that we have not included any evidence of effectiveness for aromatherapy in the prevention of PONV and that all results apply only to treatment of an existing complaint.

4.9.3 Quality of the Evidence

The included studies were comprised of six RCTs and three CCTs, with total of 402 participants. The overall quality of the retrieved evidence was low, with incomplete reporting and unavailable data hampering the comparison of most studies. Due to the age of several studies, further data were either not available
or the authors were not contactable. The nine included studies measured the effectiveness of only two aromatherapy treatments for postoperative nausea and vomiting, neither of which were shown to be effective in comparison to standard pharmacological antiemetics, although isopropyl alcohol appears to be more effective than placebo.

**4.9.4 Agreements and Disagreements with Other Studies or Reviews**

A recent systematic review of the effectiveness of non-invasive complementary therapies for reducing PONV in women having abdominal laparoscopic hysterectomy\(^{174}\) found, similarly to this review, that there was no strong evidence to support the use of aromatherapy for PONV. We have been unable to find any other systematic reviews of aromatherapy for treating PONV.

**4.10 AUTHORS' CONCLUSIONS**

**4.10.1 Implications for Practice**

From the evidence of this review, it seems that using isopropyl alcohol vapour inhalation as an adjunct therapy for PONV is unlikely to be harmful and may reduce nausea for some adult patients. It may provide a useful therapeutic option, particularly when the alternative is no treatment at all. As an inexpensive, readily available therapy (in the form of injection site 'prep-pads'), isopropyl alcohol vapour inhalation could be considered for use in situations where standard pharmacological antiemetics are unavailable, refused by patients, or contra-indicated.

Included studies that examined this intervention used one prep-pad or IPA soaked cotton ball or gauze pad per treatment and most asked the patient to take two or three deep breaths while the pad was held close to but not touching their nose. Treatments were repeated up to three times without any adverse effects being reported.

There is currently no evidence to show that using peppermint oil aromatherapy reduces PONV, but there is no evidence of its use being harmful.

**4.10.2 Implications for Research**

It is important that future trials fully report their methodology, demography and findings. Full descriptions of the results of interventions would enable clinicians to make more informed decisions about the uptake of these therapies in their clinical setting. Improved reporting would also benefit future updates of this review. There is an absence of large, well-reported trials in this area, particularly
of therapies other than isopropyl alcohol. Further studies in paediatric populations are needed before aromatherapy can be recommended for treatment of PONV in children. Future trials should include measures for longer time intervals (two to 24 hours) and report discrete data on both postoperative nausea and postoperative vomiting.

4.11 ACKNOWLEDGEMENTS

We thank Mathew Zacharias, Jung T Kim, NL Pace, Peter Kranke and Anne Lyddiatt for their help and advice during the preparation of the systematic review.

We also thank Mathew Zacharias, Katrina Farber, Milli Reddy, Jung T Kim and Janet Wale for their help and editorial advice during the preparation of the protocol for the systematic review.

The authors also wish to acknowledge Kathy Hibberd (Librarian, University of Queensland Medical Library) for her invaluable assistance in preparing the searches for this review, and Leandra Blake for her comments on the protocol. Thank you to Kate Kynoch and Lisa Brown for their assistance in testing the data extraction tool.

We also thank Marie Kristensson for the Swedish translations, Abbas Breesem for the Farsi translation, and Laurie Bay at the Institute of Modern Languages at the University of Queensland for the French translation.

4.11.1 Contributions of Authors

Conceiving the review: Sonia Hines (SH)

Designing the review: SH

Co-ordinating the review: SH

Undertaking manual searches: SH

Screening search results: SH, Elizabeth Steels (ES)

Organizing retrieval of papers: SH

Screening retrieved papers against inclusion criteria: SH, ES

Appraising quality of papers: SH, ES, Anne Chang (AC)

Abstracting data from papers: SH, ES, Kirsten Gibbons (KG)

Writing to authors of papers for additional information: SH

Providing additional data about papers: SH, AC
Obtaining and screening data from unpublished studies: SH, ES
Data management for the review: SH
Entering data into Review Manager (RevMan 5.1): SH, KG
Analysis of data: SH, KG
Interpretation of data: SH, ES, AC, KG
Writing the review: SH, AC, KG
Securing funding for the review: SH
Performing previous work that was the foundation of the present study: SH
Guarantor for the review (one author): SH
Statistical analysis: KG, SH

4.11.2 Declarations of interest

Sonia Hines: Queensland Health Nursing and Midwifery Research Grant received by Sonia Hines to assist with the conduct of the review ($5906AUD). The granting body had no influence on the findings of this review.

All other authors: No conflict of interest is known.
Chapter 5: Results

This chapter describes the findings from the Delphi process for the modification of the Beliefs About Aromatherapy Scale\(^4\) and the validation of the this modification labelled the Nurses’ Beliefs About Aromatherapy Scale (N-BAAS). Firstly, the demographic factors of the sample are described. Then the results from the initial Delphi process using the opinions of an expert panel of nurses and midwives experienced in postoperative care to make the tool more relevant to nursing practice (section 5.1) are reported followed by the results of the psychometric testing of the modified tool on a group of nursing staff (section 5.2). Finally the levels of belief in aromatherapy are presented as well as the relationship between demographic factors and respondents’ beliefs about aromatherapy are reported.

As the original BAAS tool\(^4\) was devised to measure the attitudes of herbal medicine students in the United Kingdom, checking its validity for measuring the beliefs about aromatherapy of Australian nursing and midwifery staff was required. This tool contains 19 statements about aromatherapy that ask respondents to indicate their level of agreement or disagreement on a seven-point scale. Permission for use and adaptation of the tool was received from one of its authors, Adrian Furnham.

5.1 MODIFIED BELIEFS ABOUT AROMATHERAPY SCALE

5.1.1 Participants in Delphi Process

Initially, 16 staff (4 male, 12 female) from a variety of senior positions in public and private adult hospital settings replied and agreed to take part following invitations to 38 nurses and midwives employed at Nursing Grade 6 or above, working in clinical areas caring for surgical patients. Although midwives and paediatric nurses working in surgical areas were approached to participate, none replied. The majority of panel members were Nurse Unit Managers (n = 10), with the remainder being Clinical Facilitators (n = 3), Clinical Nurses (n = 2) and Nurse Educators (n = 1). In addition, input was sought from a panel of content experts, comprised of myself, the chief supervisor and a professor of natural medicine.
5.1.2 Delphi Process Results

Opinions on the existing BAAS tool items were collected through a series of iterative rounds. Rounds continued until consensus or stability was reached\textsuperscript{175} which in this case was achieved in three rounds. For the first iterative Delphi round there were 11 returns; for round two, 9 forms were returned and for round three, 7 forms were returned.

**Round One**

The original BAAS tool and the Delphi Participant Information Sheet were distributed to the 16 participants via email. Nine replies (56.3\%) were received for the first iteration, despite reminders. At the first round, five items (4 (33.3\%), 9 (33.3\%), 11 (22.2\%), 14 (33.3\%) and 16 (33.3\%)) had levels of consensus below the cut-off point and these were deleted for the next round leaving 14 items remaining from the original scale.

During this iterative round, the panel suggested a further four items:

- Aromatherapy would benefit patients in my area of practice
- I would recommend aromatherapy to patients
- I have used aromatherapy as part of a patient's treatment.
- I have observed the use of aromatherapy as part of a patient's treatment.

These new items were added to the revised tool with a total of 18 items for the second iterative round.

**Round Two**

All nine panel members maintained their participation for the second iteration. During this round, a further two items were deemed irrelevant by the panel: item 12 (33.3\%) and 13 (44.4\%) leaving 16 items to continue to the next round.

**Round Three**

One further panel member dropped out during the third iterative round, leaving eight participants to complete the process. Interestingly, two items (22 and 23) which had previously scored quite highly failed to reach the consensus cut-off point of 75\% and were therefore deleted. There were no comments from the panel to indicate why this might be. Item 19 also failed to reach the minimum level of consensus with 62.5\% and was deleted. The deletion of these three items left 13 items.
A summary of the three Delphi rounds for determining the validity of the BAAS tool for use in measuring nurses/midwives’ beliefs in aromatherapy is provided in table 5.1.

The remaining items are all included in the final tool, but, after the modified Delphi process two additional items were added on the suggestion of the content experts: one suggested by a professor of natural medicine (item 15) and one on the basis of the findings in Chapter 4 (item 14). Therefore the final Nurses’ Beliefs About Aromatherapy Scale (N-BAAS) contains 15 items and these are shown below in Table 5.1.
### Table 5.1. Level of Relevance of N-BAAS Items for Three Delphi Rounds

<table>
<thead>
<tr>
<th>Item</th>
<th>Round 1</th>
<th>Round 2</th>
<th>Round 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Aromatherapy is based on sound scientific principles</td>
<td>77.7%</td>
<td>88.8%</td>
<td>87.5%</td>
</tr>
<tr>
<td>2. Aromatherapy should be seen as part of conventional medicine</td>
<td>77.7%</td>
<td>88.8%</td>
<td>75%</td>
</tr>
<tr>
<td>3. Aromatherapy involves changing the body as well as the mind</td>
<td>77.7%</td>
<td>88.8%</td>
<td>100%</td>
</tr>
<tr>
<td>4. I would derive great benefit from aromatherapy</td>
<td>33.3%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. The essential oils used in aromatherapy can change brain chemistry</td>
<td>77.7%</td>
<td>77.7%</td>
<td>87.5%</td>
</tr>
<tr>
<td>6. Aromatherapy can be used to treat depression</td>
<td>77.7%</td>
<td>77.7%</td>
<td>87.5%</td>
</tr>
<tr>
<td>7. Aromatherapy can be used to treat anxiety</td>
<td>88.8%</td>
<td>77.7%</td>
<td>100%</td>
</tr>
<tr>
<td>8. Aromatherapy can be used to treat phobias</td>
<td>77.7%</td>
<td>77.7%</td>
<td>87.5%</td>
</tr>
<tr>
<td>9. Aromatherapy can be used to treat schizophrenia</td>
<td>33.3%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Aromatherapy can be used to treat physical ailments such headaches, backache as well as diseases</td>
<td>77.7%</td>
<td>77.7%</td>
<td>87.5%</td>
</tr>
<tr>
<td>11. Aromatherapy can be used to treat major illnesses such as cancer or AIDS</td>
<td>22.2%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. To work as an aromatherapist, you do not need professional training</td>
<td>77.7%</td>
<td>77.7%</td>
<td>75%</td>
</tr>
<tr>
<td>13. Most psychological and medical research supports the claims of aromatherapy</td>
<td>77.7%</td>
<td>77.7%</td>
<td>87.5%</td>
</tr>
<tr>
<td>14. I would recommend aromatherapy to friends and colleagues</td>
<td>33.3%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15. Aromatherapy does not take long to work</td>
<td>77.7%</td>
<td>77.7%</td>
<td>87.5%</td>
</tr>
<tr>
<td>16. I would definitely consider aromatherapy treatment if I had an illness</td>
<td>33.3%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>17. The most important part of aromatherapy is the massage</td>
<td>77.7%</td>
<td>33.3%</td>
<td></td>
</tr>
<tr>
<td>18. The most important part of aromatherapy is the smell</td>
<td>100%</td>
<td>44.4%</td>
<td></td>
</tr>
<tr>
<td>19. Aromatherapy makes people forget about their problems</td>
<td>77.7%</td>
<td>77.7%</td>
<td>62.5%</td>
</tr>
<tr>
<td>20. Aromatherapy would benefit patients in my area of practice</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>21. I would recommend aromatherapy to patients</td>
<td>77.7%</td>
<td>87.5%</td>
<td></td>
</tr>
<tr>
<td>22. I have used aromatherapy as part of a patient’s treatment</td>
<td></td>
<td>88.8%</td>
<td>62.5%</td>
</tr>
<tr>
<td>23. I have observed the use of aromatherapy as part of a patient’s treatment</td>
<td></td>
<td>77.7%</td>
<td>62.5%</td>
</tr>
</tbody>
</table>

**NB.** The shaded areas indicate non-response by Delphi panel.
## Table 5.2. Comparison of items in Original BAAS and in the modified N-BAAS

<table>
<thead>
<tr>
<th>Original BAAS items</th>
<th>N-BAAS items</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Aromatherapy is based on sound scientific principles</td>
<td>1. Aromatherapy is based on sound scientific principles</td>
</tr>
<tr>
<td>2. Aromatherapy should be seen as part of conventional medicine</td>
<td>2. Aromatherapy should be seen as part of conventional medicine</td>
</tr>
<tr>
<td>3. Aromatherapy involves changing the body as well as the mind</td>
<td>3. Aromatherapy involves changing the body as well as the mind</td>
</tr>
<tr>
<td>4. I would derive great benefit from aromatherapy</td>
<td>Deleted</td>
</tr>
<tr>
<td>5. The essential oils used in aromatherapy can change brain chemistry</td>
<td>4. The essential oils used in aromatherapy can change brain chemistry</td>
</tr>
<tr>
<td>6. Aromatherapy can be used to treat depression</td>
<td>5. Aromatherapy can be used to treat depression</td>
</tr>
<tr>
<td>7. Aromatherapy can be used to treat anxiety</td>
<td>6. Aromatherapy can be used to treat anxiety</td>
</tr>
<tr>
<td>8. Aromatherapy can be used to treat phobias</td>
<td>7. Aromatherapy can be used to treat phobias</td>
</tr>
<tr>
<td>9. Aromatherapy can be used to treat schizophrenia</td>
<td>Deleted</td>
</tr>
<tr>
<td>10. Aromatherapy can be used to treat physical ailments such as headaches, backache as well as diseases</td>
<td>8. Aromatherapy can be used to treat physical ailments such as headaches, back ache as well as diseases</td>
</tr>
<tr>
<td>11. Aromatherapy can be used to treat major illnesses such as cancer or AIDS</td>
<td>Deleted</td>
</tr>
<tr>
<td>12. To work as an aromatherapist, you do not need professional training</td>
<td>9. To work as an aromatherapist, you do not need professional training</td>
</tr>
<tr>
<td>13. Most psychological and medical research supports the claims of aromatherapy</td>
<td>10. Most psychological and medical research supports the claims of aromatherapy</td>
</tr>
<tr>
<td>14. I would recommend aromatherapy to friends and colleagues</td>
<td>Deleted</td>
</tr>
<tr>
<td>15. Aromatherapy does not take long to work</td>
<td>11. Aromatherapy does not take long to work</td>
</tr>
<tr>
<td>16. I would definitely consider aromatherapy treatment if I had an illness</td>
<td>Deleted</td>
</tr>
<tr>
<td>17. The most important part of aromatherapy is the massage</td>
<td>Deleted</td>
</tr>
<tr>
<td>18. The most important part of aromatherapy is the smell</td>
<td>Deleted</td>
</tr>
<tr>
<td>19. Aromatherapy makes people forget about their problems</td>
<td>Deleted</td>
</tr>
<tr>
<td>20. Aromatherapy would benefit patients in my area of practice</td>
<td>12. Aromatherapy would benefit patients in my area of practice</td>
</tr>
<tr>
<td>21. I would recommend aromatherapy to patients</td>
<td>13. I would recommend aromatherapy to patients</td>
</tr>
<tr>
<td>22. I have used aromatherapy as part of a patient's treatment.</td>
<td>Deleted</td>
</tr>
<tr>
<td>23. I have observed the use of aromatherapy as part of a patient's treatment.</td>
<td>Deleted</td>
</tr>
<tr>
<td>Added</td>
<td>Added</td>
</tr>
<tr>
<td>14. Aromatherapy can be used to treat postoperative nausea and vomiting</td>
<td>15. Aromatherapy can be used in labour and delivery settings</td>
</tr>
</tbody>
</table>
5.2 TESTING AND VALIDATING THE NURSES’ BELIEFS ABOUT AROMATHERAPY SCALE

5.2.1 Sample Characteristics

Of the 1100 hard copy surveys distributed to nurses and midwives working in surgical care areas, 289 were completed and returned with 4 subsequently found to be invalid due to the respondent’s professional designation (i.e. not a registered nurse or midwife) and were excluded from the analysis, leaving 285 valid surveys returned (25.9%). The majority of respondents were female (90.5%, n = 258), registered nurses (n = 176) whose highest educational achievement was a bachelor’s degree (56.1%, n = 160), although more than a quarter of the sample had a graduate certificate or diploma (27%, n = 77). Patient care was the most common job focus (89.1%, n = 254). Very few respondents reported having qualifications in any complementary or alternative therapies (5.3%, n = 15). Age was quite evenly distributed so that 81% of the sample was aged between 26 and 55. Most respondents had been in their current position between 0-5 years (54.4%, n = 155), and a majority had been a nurse or midwife for more than 20 years (32.3%, n = 92), although years of experience were quite evenly distributed across all years (see Table 5.3.).
Table 5.3. Sample Characteristics

<table>
<thead>
<tr>
<th>Sample characteristic</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong>:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>258</td>
<td>90.5</td>
</tr>
<tr>
<td>Male</td>
<td>16</td>
<td>5.6</td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
<td>0.4</td>
</tr>
<tr>
<td><strong>Age group</strong>:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-25 years</td>
<td>33</td>
<td>11.6</td>
</tr>
<tr>
<td>26-35 years</td>
<td>81</td>
<td>28.4</td>
</tr>
<tr>
<td>36-45 years</td>
<td>78</td>
<td>27.4</td>
</tr>
<tr>
<td>46-55 years</td>
<td>72</td>
<td>25.3</td>
</tr>
<tr>
<td>56-65 years</td>
<td>16</td>
<td>5.6</td>
</tr>
<tr>
<td>66-75 years</td>
<td>2</td>
<td>0.7</td>
</tr>
<tr>
<td><strong>Highest Education Completed</strong>:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospital Certificate</td>
<td>38</td>
<td>13.3</td>
</tr>
<tr>
<td>Bachelor Degree</td>
<td>160</td>
<td>56.1</td>
</tr>
<tr>
<td>Graduate Certificate/Diploma</td>
<td>77</td>
<td>27.0</td>
</tr>
<tr>
<td>Masters</td>
<td>9</td>
<td>3.2</td>
</tr>
<tr>
<td>PhD</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Focus of main position</strong>:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient care</td>
<td>254</td>
<td>89.1</td>
</tr>
<tr>
<td>Management</td>
<td>17</td>
<td>6.0</td>
</tr>
<tr>
<td>Education</td>
<td>6</td>
<td>2.1</td>
</tr>
<tr>
<td>Research</td>
<td>4</td>
<td>1.4</td>
</tr>
<tr>
<td>Other</td>
<td>2</td>
<td>0.7</td>
</tr>
<tr>
<td><strong>Professional designation</strong>:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Registered Nurse</td>
<td>176</td>
<td>61.8</td>
</tr>
<tr>
<td>Registered Midwife</td>
<td>28</td>
<td>9.8</td>
</tr>
<tr>
<td>Clinical Nurse</td>
<td>47</td>
<td>16.5</td>
</tr>
<tr>
<td>Endorsed Midwife</td>
<td>5</td>
<td>1.8</td>
</tr>
<tr>
<td>Clinical Nurse Midwife</td>
<td>7</td>
<td>2.5</td>
</tr>
<tr>
<td>Clinical Facilitator</td>
<td>3</td>
<td>1.1</td>
</tr>
<tr>
<td>Clinical Nurse Consultant</td>
<td>2</td>
<td>0.7</td>
</tr>
<tr>
<td>Nurse Manager</td>
<td>2</td>
<td>0.7</td>
</tr>
<tr>
<td>Nurse Unit Manager</td>
<td>2</td>
<td>0.7</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Years in Current Position:</td>
<td>6.2</td>
<td>5.3</td>
</tr>
<tr>
<td>Years of experience in nursing/midwifery:</td>
<td>16.1</td>
<td>10.3</td>
</tr>
</tbody>
</table>

# = 10 cases of missing data; ## = 3 cases of missing data; ### = 1 case missing data; #### = 2 cases of missing data
5.2.2 Validity and Reliability of the N-BAAS

Validity

Preliminary examination of the BAAS indicated the potential of this scale for being used to measure nurses’ beliefs about aromatherapy. While some items demonstrated face validity, some items seem less relevant for nurses. Content validity was determined through the Delphi process as outlined above.

Exploratory factor analysis using principal axis factoring was conducted on the N-BAAS items to evaluate the construct validity of the modified tool. No previous psychometric data has been published on the original BAAS tool and consequently nothing is known about any underlying factors or constructs it may have, making exploratory factor analysis the preferable choice rather than confirmatory factor analysis. It is also important to investigate the modified N-BAAS instrument in the context of the four new items.

As the recommended sample size for a study of this type has a ratio of one item to ten respondents, a minimum of 150 respondents were required for this 15 item instrument. A total of 285 valid responses were received, which is more than adequate to conduct this analysis with a ratio of respondents per item of 19:1, which is closer to the strong subject to item ratio of 20:1 recommended by Osborne and Costello. As six of the 15 N-BAAS items have communalities exceeding 0.80 and all items exceed the recommended cut-off of 0.60, the sample size is adequate for analysing this instrument.

The appropriateness of conducting factor analysis on this data was further confirmed by the Kaiser-Meyer-Olkin level of sampling adequacy (KMO = 0.955), and the significance of Bartlett’s Test of Sphericity (P = 0.001).

Initial extraction showed two factors with eigen values above 1.0, with more than 75% of the variance explained by the first factor alone. Examination of the scree plot also showed a distinct levelling to horizontal after the second factor. Scree plot analysis is believed to be a more accurate method of identifying factors than relying on eigen values.

Factor loadings were examined using principal axis factoring using Promax oblique rotation with Kaiser normalisation (see Table 5.4). Item nine did not load onto any factor at all and was removed from the scale. Item four cross-loaded onto both factors, scoring 0.421 for factor one and 0.492 for factor two. The decision was made to retain the item on the factor with the higher loading, factor two, as the content of the item was a better fit for this factor. Factor one was
comprised of nine items and was given the label, “usefulness of aromatherapy”. The remaining five items loaded to factor two, which was labelled, “scientific basis for aromatherapy.”

Table 5.4  Factor loadings for factor analysis of N-BAAS

<table>
<thead>
<tr>
<th>Item</th>
<th>Factor 1</th>
<th>Factor 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Can be used to treat anxiety</td>
<td>1.090</td>
<td></td>
</tr>
<tr>
<td>Can be used to treat depression</td>
<td>.975</td>
<td></td>
</tr>
<tr>
<td>Can be used to treat phobias</td>
<td>.872</td>
<td></td>
</tr>
<tr>
<td>Can be used to treat headaches, backaches, &amp; diseases</td>
<td>.833</td>
<td></td>
</tr>
<tr>
<td>Can be used to treat postoperative nausea &amp; vomiting</td>
<td>.788</td>
<td></td>
</tr>
<tr>
<td>Would benefit patients in my area of practice</td>
<td>.767</td>
<td></td>
</tr>
<tr>
<td>Can be used by nurses in labour &amp; delivery</td>
<td>.711</td>
<td></td>
</tr>
<tr>
<td>I would recommend aromatherapy</td>
<td>.697</td>
<td></td>
</tr>
<tr>
<td>Does not take long to work</td>
<td>.607</td>
<td></td>
</tr>
<tr>
<td>Involves changing the body as well as the mind</td>
<td></td>
<td>.716</td>
</tr>
<tr>
<td>Based on sound scientific principles</td>
<td></td>
<td>.670</td>
</tr>
<tr>
<td>Should be seen as part of conventional medicine</td>
<td></td>
<td>.655</td>
</tr>
<tr>
<td>Essential oils can change brain chemistry</td>
<td>.421</td>
<td>.492</td>
</tr>
<tr>
<td>Most psychological &amp; medical research supports claims</td>
<td>.369</td>
<td>.467</td>
</tr>
</tbody>
</table>


**Reliability**

Internal consistency of the N-BAAS was tested with Cronbach’s Alpha ($\alpha = 0.974$) for the 14 remaining items. The two sub-scales were subjected to further reliability testing and were both found to be highly reliable with a Cronbach’s alpha for factor one of 0.967 and for factor two, 0.932. Both the findings from the factor analysis and Cronbach alpha analysis suggest that the item: “To work as an aromatherapist you do not need professional training” is different from the other items in the N-BAAS. It is likely that this item is not actually measuring a belief and this issue is discussed further in Chapter 6.
The two sub-scales were subjected to further reliability testing and were both found to be highly reliable with a Cronbach’s alpha for factor one of 0.967 and for factor two, 0.932.

5.2.3 Mean Levels of Belief about Aromatherapy

The total mean 15-item N-BAAS score was 70.3 (SD = 19.5) out of a possible score of 105. The minimum possible N-BAAS score was 15 and the maximum 105. Higher total N-BAAS scores indicated more positive beliefs about aromatherapy.

Mean scores for individual survey items ranged from 4.08 – 5.06 (out of a maximum mean score of 7), indicating a tendency towards agreement or positive beliefs about aromatherapy (see Appendix O). The two items with the lowest level of agreement and thus less positive beliefs about aromatherapy were: “Most psychological and medical research supports the claims of aromatherapy” (M = 4.08, SD = 1.54) and “Aromatherapy should be seen as part of conventional medicine” (M = 4.36, SD = 1.63).

For the two sub-scales, factor one had a mean of 42.6 (SD = 12.9) out of a possible maximum of 63 and factor two a mean of 22.1 (SD = 7.0) out of a possible maximum of 42. The mean item score for factor one was 4.85 and for factor two, 4.40, indicating positive beliefs about aromatherapy.

5.2.4 Relationships among Demographic Variables and N-BAAS

Significantly higher mean N-BAAS scores were observed in respondents with greater than five years in their current job position (t = -2.1, P = 0.03) compared to those with less than five years (Table 5.5). Significant differences were also seen between respondents holding complementary therapies qualifications (M = 76.4 SD = 15.9) compared to those without complementary therapy qualifications (M = 65.1, SD = 19.6) (t = 2.1, P = 0.02). Female respondents (M = 66.9, SD = 18.4) were more likely to have higher total N-BAAS scores than male respondents (M = 53.0, SD = 26.6) (t = 2.9, P = 0.004).

No significant differences were found between respondents with hospital or tertiary education, undergraduate or postgraduate education, patient care or non-patient care positions.
### Table 5.5. Differences between those with more or less than five years’ experience.

<table>
<thead>
<tr>
<th>Years in current post</th>
<th>N</th>
<th>Mean</th>
<th>SD</th>
<th>t-test</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up to 5 years in current post</td>
<td>155</td>
<td>63.60</td>
<td>20.75</td>
<td></td>
<td></td>
</tr>
<tr>
<td>More than 5 years in current post</td>
<td>120</td>
<td>68.70</td>
<td>18.03</td>
<td>-2.13</td>
<td>0.03</td>
</tr>
</tbody>
</table>

SD = Standard Deviation

### 5.3 SUMMARY

The original BAAS instrument\(^48\) has been modified into a tool which can measure nurses’ and midwives’ beliefs about aromatherapy. Validity of the tool was established by a panel of experienced nurses and a group of content experts who found the items on the modified N-BAAS instrument were relevant to nursing practice. The N-BAAS tool has internal consistency.

Initial construct validity was supported by factor analysis of the instrument’s items showing two clear components, or factors, onto which all 14 valid items load. These two factors, “usefulness of aromatherapy” and “scientific basis of aromatherapy” describe two distinct domains of the scale and may assist in further understanding of the scale results when applied to participants. This is discussed in more depth in Chapter Six.
Chapter 6: Discussion

This chapter describes and discusses the results of the two parts of this work and situates them in the context of the current literature. The chapter is arranged in the two arms of the work – that is, in terms of examining the effectiveness of aromatherapy for postoperative nausea and vomiting, and modifying and testing the Nurses’ Beliefs About Aromatherapy Scale.

Section 6.1 discusses the evidence of the effectiveness of aromatherapy for postoperative nausea and vomiting as found in the results of the systematic review, the strength of the findings and how the systematic review findings are situated in the existing complementary therapies literature. The levels of evidence in the findings are explored and the grading system described. The relationship between the systematic review findings and the use of aromatherapy for PONV in clinical practice is also discussed. Gaps in the literature are also described.

Section 6.2 discusses the modification of the Beliefs About Aromatherapy Scale in terms of the meaning of the Delphi process results, the conduct of the process and the issues that arose. This is further divided into examination of the analysis of the N-BAAS instrument, the value of the individual remaining items and those items that were deleted. The findings of the exploratory factor analysis are analysed in depth and discussed in terms of the application of the N-BAAS tool.

The testing of the modified scale is discussed in section 6.3. This is further divided into examination of the analysis of the N-BAAS instrument, the value of the individual remaining items and those items that were deleted. The findings of the exploratory factor analysis are analysed in depth and discussed in terms of the application of the N-BAAS tool. Additionally, the results of the pilot survey are discussed.

6.1 Effectiveness of Aromatherapy to Treat Postoperative Nausea and Vomiting

6.1.1 Summary of Systematic Review Results

Only two therapies were able to be included in the systematic review in Chapter 4: isopropyl alcohol and peppermint oil. These two substances were compared to a number of different antiemetic drugs as well as placebo. Despite the wide range of aromatherapy delivery modes used in practice, such as massage,
dispersal by oil burner, or direct application to the skin, all aromatherapy in the studies included in the systematic review was delivered via direct inhalation. Due to the small number of studies able to be included (n = 9) the findings are based on only 402 participants and the majority were women. Studies were set in both inpatient post-anaesthesia care units and same day surgery units, measuring such outcomes as: the use of 'rescue' antiemetics, number of nausea and vomiting events, severity of nausea, time to reduction in nausea, patient satisfaction, recurrence of symptoms, and cost of treatment.

Peppermint oil insufflations are commonly recommended for nausea and vomiting\textsuperscript{11, 154, 173} but there is little evidence to support the use of peppermint oil for PONV. Two included studies examined the use of peppermint oil as a treatment for PONV\textsuperscript{14, 162} of which only Anderson\textsuperscript{162} was adequately randomised and blinded. Tate\textsuperscript{14} reports evidence of an effect, but concerns about randomisation, blinding and outcome measurement in the methods of this study mean that these results should be viewed with caution. Anderson\textsuperscript{162} found that the effect of peppermint oil insufflation was not statistically different from the effect of insufflations of isopropyl alcohol or saline and hypothesised that the observed effect was instead due to the deep breathing participants were instructed to do as part of the intervention.

Several studies included in the systematic review tested the effect of isopropyl alcohol (IPA)\textsuperscript{15-19, 39, 40}, both against standard antiemetic drugs and against other aromatherapies and placebo, in both adults and children. When compared to saline placebo, IPA appears to be effective in reducing the number of doses of rescue antiemetics participants require\textsuperscript{16, 39} and in providing short-term relief of symptoms in children\textsuperscript{122}.

Additionally, IPA was found to act more quickly to relieve symptoms. In two studies\textsuperscript{17, 18} IPA provided faster time to 50% relief of symptoms than ondansetron and, in a third study\textsuperscript{19}, IPA provided faster relief than promethazine. These results appear to have been short-term, as when the results were combined in a meta-analysis there was no statistically significant difference in the number of participants requiring rescue antiemetics in the combined results of these three studies.

All studies that measured patient satisfaction with aromatherapy\textsuperscript{16, 18-20} found that participants were satisfied with the treatment\textsuperscript{17-19, 162}, reporting high levels of satisfaction with their experience. It should be noted that all participants (treatment and comparison groups) in these studies reported high levels of satisfaction with no significant differences between the groups and it is possible
that the increased attention to assessing and treating PONV in these patients led to this result.

**6.1.2 Levels of Evidence in the Systematic Review**

GRADE Working Party\textsuperscript{180} levels of evidence were calculated and reported for the two of the meta-analysed outcomes, “isopropyl alcohol compared to standard treatment for treatment of postoperative nausea and vomiting” and “isopropyl alcohol compared to saline for treatment of postoperative nausea and vomiting” (tables 4.3 and 4.4). In both cases the levels of evidence were found to be low. In terms of the GRADE levels of evidence, this means that “further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate” (p. 926)\textsuperscript{180}. This is a conservative rating made in consideration of methodological flaws in some of the included articles.

The GRADE levels of evidence were developed in response to the need for consistent communication of the strength of recommendations from guidelines and systematic reviews\textsuperscript{180}. The four levels of evidence: high, moderate, low, and very low, are used to describe the authors’ confidence in the recommendations\textsuperscript{180}. Randomised controlled trials, while considered high quality evidence in their optimal form, may have their level of evidence reduced by factors such as: study limitations, inconsistency of results, indirectness of evidence, imprecision and/or reporting bias\textsuperscript{181}.

So, in the case of the systematic review in Chapter 4, while the included studies were predominantly randomised controlled trials, weaknesses in blinding, allocation concealment, small sample sizes and small effect size reduced the quality of evidence to low. Lack of reporting of adverse effects also means that a stronger finding is not warranted\textsuperscript{182} as it is not possible to judge the balance between the reported benefits of the intervention with any possible associated harms.

**6.1.3 Adverse Effects Reported in Studies Included in the Systematic Review**

Research has found that many users of complementary therapies believe them to be safe\textsuperscript{183} but this is far from the case. As with all pharmacologically active substances, complementary therapies may cause a range of adverse effects, either on their own or in interaction with medications\textsuperscript{183}. Reporting of adverse effects of complementary therapies largely occurs on an *ad hoc* basis, when
serious adverse effects occur and are reported to the relevant health authority, rather than as a regular feature of research publications 184-186.

No adverse reactions were reported by any of the studies included in the systematic review (section 4.6.3). It is not known whether there are no adverse effects reported because none occurred or if no data was collected on this outcome. Reporting of adverse effects in studies of complementary and alternative therapies is not consistent, with many studies failing to adequately address this outcome in their publications186. As previously highlighted, reporting of complementary therapy research is often incomplete, and studies using flawed methods are not uncommon.

Aromatherapy has been known to cause a range of adverse effects, although these are not common11. Peppermint oil has been associated with bronchial or laryngeal spasm in children187 and urticaria, dermatitis, and gastro-intestinal upset in adults188, 189. Most adverse effects with peppermint essential oil have been associated with oral administration, or copious use of the oil on the skin190. While inhalation aromatherapy with peppermint oil is generally considered to be low-risk190, it is not completely without risk and inclusion of adverse effects as an outcome in research studies can only improve the knowledge base for this intervention.

Isopropyl alcohol, while not an essential oil, is reported to be a traditional remedy for nausea and vomiting in South America, although the origins of this belief are unclear50, 86, 162. It has the potential to cause serious and significant adverse effects, particularly if misused, but the lethal dose of IPA in humans is believed to be approximately 1 mg/kg191, 192, which seems unlikely in the context of aromatherapy use. Small traces of alcohol can be absorbed into the blood through insufflation of the vapours106, which may be undesirable for some patients, particularly those with a previous history of alcohol dependence or abuse, or those who wish to avoid all alcohol ingestion. Used as directed, isopropyl alcohol aromatherapy would seem to have low potential for causing adverse effects.

6.1.4 Agreement and Disagreement with Other Studies or Reviews

While the findings of most published research studies appear to favour the use of aromatherapy for PONV, the findings from previous systematic reviews are less positive. As the evidence for and against aromatherapy for PONV strongly illustrates that research studies with less methodological rigour are more likely to show evidence of an effect193, it is likely that systematic reviews including a
preponderance of unblinded and non-randomised studies will find greater evidence of an effect also. For that reason, only well-conducted systematic reviews of controlled experimental trials are mentioned here.

In addition to the systematic review in Chapter 4 of this work, there are two other systematic reviews examining the effectiveness of aromatherapy for PONV\(^{174, 190}\). A 2009 systematic review on the effectiveness of non-invasive complementary therapies for reducing PONV in women having abdominal laparoscopic hysterectomy\(^{174}\) found, similarly to the systematic review in Chapter 4, that there was no strong evidence to support the use of aromatherapy for PONV. In comparison with the systematic review in Chapter 4, Hewitt and Watts only included the studies of isopropyl alcohol and ondansetron by Cotton\(^{17}\) and Winston\(^{18}\), excluding the studies by Anderson and Gross\(^{162}\), Merritt\(^{40}\), and Tate\(^{14}\) for being outside the inclusion criteria. The studies by Kamalipour\(^{16}\), Langevin\(^{39}\), Pellegrini\(^{19}\), and Wang\(^{122}\) are not mentioned.

Keifer et al.’s systematic review of peppermint oil makes brief mention of the use of the inhaled vapours for treating PONV\(^{190}\). Similarly to the findings here, Keifer et al. found little evidence to recommend peppermint oil for treating PONV\(^{190}\). The methodological weaknesses of the study by Tate (lack of randomisation and blinding) are highlighted, as are the small sample size and marginally significant effect size in the experimental group (\(P = 0.0487\))\(^{190}\). In agreement with the recommendations in Chapter 4, Keifer et al. also suggest that further research on this intervention should be conducted\(^{190}\).

### 6.1.5 Complementary Therapies Research

Research in complementary therapies has long been problematic, plagued by poor research designs and over-optimistic interpretations of findings in many cases\(^{194, 195}\). Rigorously conducted research into complementary therapies exists, of course, but there are those that argue that complementary therapy interventions do not fit well with the biomedical model of the randomised controlled trial and should therefore be judged by different criteria\(^{196-198}\). Contrary to this opinion, many of the studies included in the systematic review in this work show that scientific rigor and complementary therapies are not mutually exclusive.

The tension between the two schools of thought on complementary therapies and medical science, which has often led to complementary therapies being dismissed as “completely ineffective” and “unscientific”\(^{199}\) by one side and mainstream medical treatments dismissed as a tool of powerful pharmaceutical
interests by the other. Neither of these extremes seems helpful in improving understanding of new and existing therapies, whatever their origin. Preferable, rather, is a degree of pragmatism and moderation as recommended by Ernst, who states that the best way forward for complementary therapies is through rigorous research.

A complementary therapy such as aromatherapy, the effectiveness of which should not be highly dependent on the skill of the therapist or their relationship with the patient (factors often used to argue against the use of experimental trials in complementary therapies) lends itself well to testing with randomised controlled trials and indeed where the impact of variability between therapists on measured outcomes is a concern, tools exist to account for any possible confounding.

Studies such as that by Tate show that aromatherapy trials can include blinding of participants with sham treatments. Sham treatments are those which mimic the scent of the ‘active’ treatment in order to conceal to both participants and assessors the group allocation of each participant. Tate used peppermint essence as a sham aromatherapy treatment to test if there was a difference between the effect of peppermint essential oil and a peppermint-scented substance. Sham treatments have been used to blind participants in other aromatherapy studies which also failed to find significant evidence of an effect.

Blinding of outcome assessors in trials of aromatherapy would add greatly to their methodological rigour, as unblinded assessors have been found to overestimate effects by more than 30%. Overall, increased attention to methodological rigour in the design of studies of aromatherapy would greatly strengthen the body of evidence on this therapy.

### 6.1.6 Gaps in the Current Evidence Base

Currently there is much we do not know about the use of aromatherapy for PONV. The mechanism of its effect, if there is one, is still a subject of debate. It is not known whether environmental exposure to the vapours of essential oils can cause enough of an active ingredient to be absorbed into the body to cause a physiological reaction or if the effect seen in trials of aromatherapy is being caused by the triggering of memories and previous experiences of the scent.

Regardless of the mechanism of action, it is still important that other gaps in the current evidence-base are recognised and addressed. While isopropyl alcohol for
treated PONV has been tested and found effective in randomised controlled trials, these trials have frequently lacked methodological rigour. As previously discussed in Chapter 2, it is recommended that outcome data is collected up to 24 hours postoperatively in all trials of treatments for PONV76. None of the trials of isopropyl alcohol included in Chapter 4 measured outcomes to 24 hours and most only collected data for 2 hours after surgery15-19, 39, 40, 122. This leaves a significant gap in our knowledge about the effectiveness of isopropyl alcohol for treating PONV at those time-points greater than two hours.

Even less is known about the effectiveness of peppermint essential oil for treating PONV. While two trials14, 162 were included in the systematic review in Chapter 4, only one found any evidence of an effect and those results are made suspect by the study’s poor research methods and reporting14. Despite the methodological flaws of Tate’s study, it remains widely cited within the literature205-208, which indicates a pressing need for stronger evidence to supersede it and strengthen the foundation for future research.

The other major gap in the current body of aromatherapy research is whether the effect on PONV is truly being caused by the substance at all, or simply a by-product of the deep, controlled breathing participants are being instructed to do as part of receiving the intervention. It is known that deep breathing can have an effect on easing nausea209 and in PONV it is theorised deep breathing may also increase clearance of anaesthetics and other nausea-inducing drugs210. The observed effect from deep breathing may also be due to the close proximity of the chemoreceptor trigger zone of the brain (the part of the brain in the area postrema of the medulla oblongata which controls nausea and vomiting) to the breathing centre in the brain stem56. Whatever the mechanism of this effect, it seems important that future trials of aromatherapy for PONV consider this possibility and, as Hewitt and Watts suggest, add a control arm to explore the effect of deep breathing instruction alone on rates and severity of nausea and vomiting174.

6.2 MODIFICATION OF THE BELIEFS ABOUT AROMATHERAPY SCALE

6.2.1 The Delphi Panel
The senior registered nurses who took part in the Delphi panel process were in positions such as Nurse Unit Manager, Clinical Facilitator, Clinical Nurse and Nurse Educator. As nurses in these professional designations are in a position to influence practice within their clinical areas and are likely to have significant
clinical experience, it was considered that this group was both suitable and representative enough to form a panel for the Delphi process, although it was a concern that no midwives, or nurses from paediatric settings agreed to participate.

There are no set criteria for the selection of experts, and it is recommended that researchers use ‘common sense’ and practicality\textsuperscript{145}. Indeed there is no single definition of ‘expert’ either, with the word in the context of a Delphi panel being defined as a group of informed individuals, specialists in their field, or someone who has specific subject knowledge\textsuperscript{147}. It is possible for bias to be introduced into the Delphi process through selection of the panel\textsuperscript{147}. The types of individuals who are happy to be identified as subject experts, and who have the time and inclination to participate in the Delphi process may well have different opinions from the population at large and without sampling the wider population it is impossible to know if this is the case.

The entire process, from the initial contact through all the iterative rounds, was conducted using email. This had both benefits and shortcomings. This may have meant there were some potential participants who did not see their invitation due to absence or clinical workload, or because they infrequently check their email. Experience with this population has shown there are a considerable number of ‘bedside’ nurses and midwives who rarely or never access their employer-provided email, but this is less of a problem with clinicians in management and education positions.

But a benefit of using email to complete the process was that participants in this Delphi panel were able to remain anonymous to the group. No single participant’s opinions or feedback was identified as belonging to them in communications with the group. This had several advantages. There was less pressure for participants to agree with the majority opinion and because panellists did not know the identity of their fellow participants, they could not be swayed by their prior knowledge of any participant or their reputation\textsuperscript{141}. Participants were able to give their opinions about the relevance of the instrument’s items without fear or favour.

6.2.2 Delphi Process

This Delphi process utilised a structured approach in the first round, rather than the unstructured, opinion-gathering approach of the ‘classic Delphi’\textsuperscript{141}. The original BAAS instrument was used as the stimulus to prompt panellists’ responses about nurses’ and midwives’ use of aromatherapy in practice. This
allowed the process to remain focussed, and lessened the time and effort burden on panellists. This modified approach or ‘reactive Delphi’ has been used extensively in nursing research\textsuperscript{144}.

Time and participant burden were also considered when it was decided to limit the Delphi process to a predefined number of rounds. Prior to the start of the process, a limit of three iterative rounds was set. There is no universally agreed number of rounds required for a Delphi process; two, three or four rounds, or more (if needed) have been recommended, but the burden of a large number of iterations on the Delphi panel should be considered\textsuperscript{146}. It was for these reasons that the number of rounds for this Delphi process was limited to three.

### 6.2.3 Additional Items

Six additional items were suggested by the Delphi panel and the content experts during the course of modifying the BAAS instrument. Four of these items were suggested by Delphi panellists and two by the content experts. In contrast to the deleted items, these items are largely focused on patients and patient care. These can be divided into two broad themes: a) uses of aromatherapy in practice; b) individuals’ use of aromatherapy in practice.

**a) Uses of aromatherapy in practice**
- Aromatherapy would benefit patients in my area of practice
- Aromatherapy can be used in labour and delivery settings
- Aromatherapy can be used to treat postoperative nausea and vomiting

**b) Individuals’ use of aromatherapy in practice**
- I would recommend aromatherapy to patients
- I have used aromatherapy as part of a patient’s treatment.
- I have observed the use of aromatherapy as part of a patient's treatment.

The addition of these items increases the N-BAAS instrument’s focus on nursing practice and the benefits of aromatherapy to patients, but not all of these items were carried through to the final version of the N-BAAS instrument. Two items suggested by Delphi panellists in round one were rejected in round two. The items, “I have used aromatherapy as part of a patient’s treatment” and “I have observed the use of aromatherapy as part of a patient’s treatment” achieved only 62.5\% consensus and were deleted from the final tool. The one remaining item from this group, “I would recommend aromatherapy to patients” is more
action-oriented than the other two items and it may be that this was why it was retained for the final version of the instrument.

6.2.4 Deleted Items
Nine of the original 19 BAAS items and two of the additional items suggested by panellists failed to reach the 75% consensus level and were deleted from the modified scale. These deleted items could be grouped into three broad concepts or themes: a) “I” statements about personal use of aromatherapy; b) Exaggerated claims about aromatherapy; c) Elements of aromatherapy that are “important”. Delphi panel participants were not asked for their reasons for labelling individual items as ‘irrelevant’ or ‘very irrelevant’ but given the commonalities between the deleted items, it is possible to speculate on some potential reasons for their deletion.

a) “I” statements about personal use of aromatherapy:
- I would derive great benefit from aromatherapy
- I would definitely consider aromatherapy treatment if I had an illness
- I would recommend aromatherapy to friends and colleagues
- I would definitely consider aromatherapy treatment if I had an illness
- I have used aromatherapy as part of a patient’s treatment
- I have observed the use of aromatherapy as part of a patient’s treatment

Delphi panel participants were instructed to consider the relevance of each item to nursing and/or midwifery practice. It seems that these items about personal preferences and practices regarding aromatherapy might have been viewed as being irrelevant because the nurse’s or midwife’s personal feelings about, or use of, an intervention has little to do with its effectiveness or its suitability for use in practice. It is also possible that the Delphi participants were drawing a distinct conceptual line between the personal and the professional; some authors have noted a difference between health professionals’ personal use of complementary therapies and their professional use or acceptance of patients’ use. This possibility is given further weight when the additional item suggested by the Delphi panel, “Aromatherapy would benefit patients in my area of practice” is considered.

b) Exaggerated claims about aromatherapy
- Aromatherapy can be used to treat schizophrenia
- Aromatherapy can be used to treat major illnesses such as cancer or AIDS
- Aromatherapy makes people forget about their problems

The Delphi panel seemed to be leaning towards a cautious appraisal of aromatherapy which is in line with previous findings about nurses and their views of complementary therapies\cite{44,128}. While there is evidence to suggest that aromatherapy can have an effect on symptoms such as agitation\cite{24}, chemotherapy-induced nausea\cite{212}, pain\cite{26,213} and depression\cite{214}, to state that aromatherapy can ‘treat’ serious conditions such as schizophrenia, cancer and AIDS, or make people ‘forget about their problems’ is likely to be an overstatement of its capabilities.

c) Elements of aromatherapy that are “important”.

- The most important part of aromatherapy is the massage
- The most important part of aromatherapy is the smell

In terms of nursing practice, if a patient is given a massage with aromatherapy oils it is relatively unimportant to the recipient whether the benefit is based in the massage process or the scent of the oil\cite{215} as they are inseparable parts of the procedure. Or conversely, the panellists may have not considered massage a ‘true’ part of aromatherapy at all, defining aromatherapy as solely the inhalation of the vapours of the substances. While aromatherapy massage is a subset of aromatherapy practice\cite{11} there are many different modalities through which it can be delivered.

### 6.3 TESTING OF THE MODIFIED N-BAAS TOOL

#### 6.3.1 Psychometric Testing of the N-BAAS Tool

Two hundred and eight-five nurses and midwives completed and returned the Nurses’ and Midwives’ Beliefs About Aromatherapy survey. The majority of the respondents were female registered nurses aged 26-55 years, educated to a Bachelor Degree level, and working in patient care settings. Very few had completed any qualifications in complementary and alternative therapies. Most had been in their current work position approximately six years and had been a nurse or midwife for approximately 16 years.

The original Beliefs About Aromatherapy Scale instrument\cite{48} has been modified into a tool which measures nurses’ and midwives’ beliefs about aromatherapy. A panel of experienced nurses and a group of content experts found that the items
on the modified N-BAAS instrument are relevant to nursing practice. The N-BAAS tool has both internal consistency and reliability.

Factor analysis of the instrument’s items shows two clear sub-scales, onto which all 14 valid items load. These two sub-scales, “usefulness of aromatherapy” and “scientific basis of aromatherapy” describe two distinct domains of the scale and may assist in further understanding of the scale results when applied to participants.

Analysis of the results of the survey indicates that respondents generally have positive beliefs about aromatherapy and that higher total N-BAAS scores are significantly associated with having attained complementary and alternative medicine qualifications, although the proportion of the sample holding CAM qualifications was very small (n = 15). The only other demographic factor with any significant association with higher total N-BAAS scores is having greater than five years in the current job position.

6.3.2 Representativeness of the Sample

A common problem with self-selected samples is that they may not be representative of the population they are meant to represent. The surveys in this study were distributed by hand to clinical areas within the study hospitals and left in staff common areas with instructions on how to complete after a discussion about the survey with the unit manager or their delegate. Nurses and midwives could then decide for themselves whether to complete the survey and place it in the return box. The risk to the survey’s validity in this is that those staff who chose to complete and return a survey could have been somehow different from the larger population of nurses and midwives. From the demographic data collected in the survey, it does not seem this was the case.

Nurses and midwives working outside of bedside clinical areas are not well-represented in this sample, which is probably due to the placement of the survey forms and collection boxes, which were left in the staff common areas of patient care units in the study hospitals. As the aim of the survey was to determine the beliefs about aromatherapy of nurses and midwives caring for surgical patients, this is not necessarily a shortcoming, as the opinions of staff who would potentially be using aromatherapy in practice were considered to be of most interest.

Australian Institute of Health and Welfare (AIHW) data shows that the demographics of the survey sample is quite similar to the demography of the nursing population at large. Just over 90% of the Australian nursing workforce
(including midwives) is female and 78% are involved in providing direct patient care and the average age for a registered nurse was 43.7 years (2007 data)\textsuperscript{216}. The education data collected by AIHW does not report different nursing and tertiary qualifications in the way they have been collected here, so it is not possible to compare those figures.

The sample was also adequate to conduct the planned factor analysis. With 15 items and 285 respondents, the ratio of respondents to survey items was 19:1, which is above the planned 10:1 threshold and close to the 20:1 level recommended by Osborne and Costello\textsuperscript{178} for “strong” respondent to item ratio.

### 6.3.3 Factor Analysis for Determining Construct Validity

Exploratory factor analysis (EFA) was conducted on the N-BAAS items to evaluate the construct validity of the modified tool. EFA is most useful for exploring a data set and making inferences about it, but not for testing hypotheses\textsuperscript{179}. As no prior psychometric data has been published on the original BAAS instrument\textsuperscript{48} and nothing was known about any underlying factors it may have, an exploratory approach was considered more appropriate for the instrument\textsuperscript{217}. When conducted on variables with low communalities EFA can result in substantial distortion in results\textsuperscript{218}, but the data in this study (except for one item that was later removed) had relatively high communalities (>0.60) which makes this unlikely and strengthens the case for EFA.

Principal axis factoring was chosen as the method of factor analysis for this study as it is recommended for data that is not normally distributed\textsuperscript{218}, which was the case with the data from this survey. A factor loading cut-off of 0.4 was used, which is generally recommended in the literature\textsuperscript{218}. Principal components analysis was initially considered; however this only showed one factor, when it was felt the content of the scale items was more diverse than that. Principal axis factoring has been shown to better recover even weak factors\textsuperscript{219} and this proved to be more suitable method.

Initial extraction showed two factors with eigenvalues above 1.0, with more than 75% of the variance explained by the first factor alone. Examination of the scree plot also showed a distinct levelling to horizontal after the second factor, which indicates the number of factors that should be retained\textsuperscript{220}. Scree plot analysis is believed to be a more accurate method of identifying factors than relying on eigenvalues alone\textsuperscript{179}.

After initial extraction, promax oblique rotation was used to derive the factors in this analysis. Promax rotation, while used less frequently than varimax or
oblimin rotations, has the advantage of being conceptually simple\textsuperscript{221} and oblique rotations are more useful when it is likely the items are correlated\textsuperscript{222}, which these were expected to be. Rotation is conducted to distribute the variance in the data across factors to maximize the loadings of items on factors, thereby producing a solution\textsuperscript{223}. When principal axis factoring with promax rotation was applied to the data set from the Nurses’ and Midwives’ Beliefs About Aromatherapy Survey, two clear factors emerged in the pattern matrix.

6.3.4 Sub-scales

The two factors or sub-scales that emerged from the factor analysis described above were labelled, “usefulness of aromatherapy” and “scientific basis of aromatherapy” as these concepts seemed to be common to the items grouped under them and it was important to give the sub-scales meaningful names. Labelling of the sub-scales assists in clarifying the meaning of the underlying dimensions in the data they represent\textsuperscript{223}. Nine factors loaded onto sub-scale one and five to sub-scale two. There is no set number of items that is required to constitute a factor or sub-scale, other than the number must be two or more, but probably a minimum of three to five is preferable\textsuperscript{223}.

Sub-scale one, “Beliefs about the usefulness of aromatherapy” is the most important factor on the scale, accounting for over 75% of the variance. It can be seen from the content of these items that they reflect a variety of uses for aromatherapy, hence the label, “beliefs about the usefulness of aromatherapy” was considered appropriate. This factor measures nurses’ and midwives’ beliefs about the different ways they may use aromatherapy, or ways they may encounter patients using aromatherapy. This is an important and necessary function for a scale to measure nurses’ and midwives’ beliefs about aromatherapy; without belief in the usefulness of a therapy, staff are unlikely to implement it in practice\textsuperscript{138}.

These five items that comprise the second sub-scale, “beliefs about the scientific basis of aromatherapy” reflect questions about the actions and scientific basis of aromatherapy, and so this factor has been labelled, “beliefs about scientific basis of aromatherapy.” The items appear to be measuring the respondent’s beliefs about the science underlying aromatherapy and how it acts on the body. Although this second factor is much weaker than the first, accounting for less than 5% of the variance, and therefore could have been deleted on the basis of statistical unimportance to the scale overall\textsuperscript{224}, it was retained due to the value of understanding respondents’ beliefs on this topic.
Both of these factors are important for understanding the beliefs of potential users of aromatherapy. Knowledge about the wide range of applications aromatherapy may have is essential before it can be used in practice, but having an idea about the scientific basis of aromatherapy is important as well. Having a healthy scepticism about the actions of any complementary therapy is important; and responses to these factors may also indicate that. The combination of these two factors helps to generate a theory\textsuperscript{222} that beliefs about aromatherapy are a function of beliefs about the usefulness and beliefs about the scientific basis of aromatherapy.

This is further supported by looking again at the PARIHS framework discussed in Chapter Two, which refers to the need for staff to perceive that the evidence is both useful and scientifically robust\textsuperscript{138}. It could be inferred from this that respondents who score highly on the N-BAAS are more likely to participate in a successful implementation of aromatherapy into practice.

One item did not load onto either sub-scale and was deleted from the analysis. The item, “To work as an aromatherapist you do not need formal training” was a poor fit to the rest of the items on the scale both in terms of wording and meaning. Rather than a belief, this item seems to be asking about respondents’ knowledge about the regulatory requirements of particular health jurisdictions. For some health systems, aromatherapy practitioners will be required to have formal training, and in others, anyone who desires to do so may call themselves an aromatherapist. For instance, in Australia, aromatherapists wishing to have their consultation fees reimbursable by private health insurance must have completed a formal college qualification and have registered with the relevant professional body\textsuperscript{225}. This item seems to be a knowledge item and not a statement of belief and so does not properly belong on the N-BAAS instrument.

It was also the only item with low communality, with a score of 0.19. Excluding the item increased the reliability of the scale to Cronbach’s $\alpha = 0.974$, while leaving the other items still loading onto the two factors. Deleting problematic items and re-running the analysis is recommended if it has no effect on the integrity of the data\textsuperscript{179}. Removal of this item does not seem to decrease the utility or the reliability of the scale and in fact seems to be beneficial to it.

### 6.3.5 Future Modifications to the Scale

Part of the function of factor analysis is to reduce the number of variables in the scale so the least number of variables best produce the required data\textsuperscript{226}. In the process of factor analysis to modify an existing instrument, it is likely that some
items will emerge as duplicate or extraneous. These possibly redundant items may measure the same concept or belief in a way so similar to another item or items that their deletion will not change the function of the instrument.

It is quite possible that several of the items on the modified N-BAAS instrument are measuring the same belief and so could safely be deleted. Items such as, “Aromatherapy would benefit patients in my area of practice,” and “I would recommend aromatherapy to patients,” are conceptually very similar so it seems that little would be lost by deleting one. In addition, three items from the second factor, “Aromatherapy is based on sound scientific principles,” “Most psychological and medical research supports the claims of aromatherapy,” and “Aromatherapy should be seen as part of conventional medicine,” are also very similar in meaning and intent. It seems likely that the N-BAAS instrument would not be any less valid or reliable with the exclusion of one or two of these items. Further testing is required to determine which, if any, items are redundant.

Regardless of this, it should be remembered that the Delphi panel rated these items as relevant to nursing practice and should be included in the modified instrument. For this reason, despite the quite obvious similarities between these items, the items were retained in the instrument.

### 6.3.6 Nurses’ Beliefs About Aromatherapy

For nurses’ and midwives’ beliefs about the usefulness of aromatherapy the moderate to high mean score indicates respondents held mostly positive beliefs about the items in this sub-scale. This is supported by a variety of research studies of nurses and midwives in a range of international healthcare settings which found that nurses and midwives generally have positive beliefs about aromatherapy and either use it in practice already or would like to use it if their institution permitted it. Respondents’ beliefs about the scientific basis for aromatherapy were slightly less positive, which probably represents a healthy scepticism about a therapy with a multitude of claims of effect and somewhat smaller amount of rigorous research.

Even if nurses and midwives have generally positive beliefs about aromatherapy, it does not then automatically follow that they will be prepared and able to use aromatherapy in practice. There may be several barriers to including aromatherapy as a nursing intervention equivalent to non-pharmacological pain therapies such as hot compresses or ice-packs. Some research has found that nurses do not view aromatherapy as fitting into the medical model of care and they have little confidence in their ability to change the status-quo.
These perceived barriers may be due in part to the tension between what has been described as a “techno-curative, positivist and scientific model” of nursing and a more holistic and patient-centred model. Johnson proposes that the popularity of aromatherapy itself is a response to the loss of ‘hands-on’ practices such as back-rubs in modern nursing practice. It is possible that a greater emphasis on evidence-based aromatherapy practice, with strong research and standardised practices, may decrease some of this tension and provide a middle ground acceptable to both schools of thought.

Despite these barriers, many Australian nurses are enthusiastic users of complementary therapies, including aromatherapy. Over 80% of respondents to a survey conducted by the Australian Nursing Journal were utilising complementary therapies in their personal lives. Nurses in Leach’s 2002 study agreed that complementary therapies were “safe, effective and result in a positive patient outcome.” Similarly, the findings of Leach’s pilot survey of Australian nurses and midwives show they have positive beliefs about aromatherapy and this is likely to lead to greater use in practice if institutional and cultural barriers can be overcome.

6.4 SUMMARY

The two arms of this work, the systematic review, and the modification and testing of the Nurses’ Beliefs About Aromatherapy Scale, have shown that aromatherapy can be used as an adjunct treatment for postoperative nausea and vomiting and that nurses and midwives have overall positive beliefs about the use of this therapy in practice. The modified N-BAAS instrument is valid and reliable for measuring beliefs in this population, but further testing is required to validate it for use in diverse settings and populations. The limitations of this work, the implications for clinical practice and for future research are discussed in Chapter 7.
This chapter contains the conclusions (section 7.1), limitations (section 7.2), and the implications for clinical practice (section 7.3) of this work. Implications for further research are discussed in section 7.4. Conclusions from the two arms of the work are described in terms of the four research questions listed in Chapter 1, the limitations of all the parts of the work are discussed and recommendations are made for clinical practice.

7.1 CONCLUSIONS

This work sought to answer four research questions, which reflect the two arms of the systematic review and research studies.

7.1.1 Is aromatherapy an effective treatment for postoperative nausea and vomiting?

From the findings of the systematic review, it seems that aromatherapy with isopropyl alcohol has an effect on reducing the number of doses of rescue antiemetics needed by patients that is greater than the effect of a placebo but not greater than standard antiemetics. It cannot be stated definitely that aromatherapy with isopropyl alcohol has an effect on the length and severity of PONV due to a lack of suitable data for a meta-analysis. Patients who receive aromatherapy for their PONV are generally satisfied with their treatment.

7.1.2 Can aromatherapy be used to treat postoperative nausea and vomiting with clinical safety comparable to that of pharmacological antiemetics?

From the findings of the systematic review it is not possible to give a definitive statement about the clinical safety of aromatherapy. No adverse effects were reported by any of the studies included in the systematic review. Aromatherapy can have adverse effects, but these usually occur when it is misused\textsuperscript{215}, or the recipient is allergic to the particular substance\textsuperscript{235}. It is likely that used within clinical guidelines, aromatherapy can be used safely and with no greater risk to patients than pharmacological antiemetics.
7.1.3  Is the Beliefs About Aromatherapy Scale relevant to nursing and midwifery practice or does it require modification before use with a population of nurses?

The original Beliefs About Aromatherapy Scale was not designed for use with nurses or midwives. The Delphi panel process showed that the original BAAS instrument was not completely relevant to nursing and midwifery practice. The Delphi panel of nurses and a group of content experts modified the instrument to remove items that were irrelevant to nursing and midwifery practice and to include items of relevance, enabling the tool to collect data on nurses’ and midwives’ beliefs about aromatherapy.

7.1.4  Is the modified Nurses’ Beliefs About Aromatherapy Scale valid and reliable?

The modified Nurses’ Beliefs About Aromatherapy Scale is both valid and reliable for measuring respondents’ beliefs about aromatherapy. A panel of expert registered nurses confirmed face validity of the scale. Construct validity was established by factor analysis, which showed that the modified scale contains two distinct sub-scales, ‘the usefulness of aromatherapy’ and ‘scientific basis of aromatherapy’. The reliability of the entire scale as well as each of the sub-scales is high. Face and construct validity of the scale were confirmed by a panel of expert registered nurses.

7.2 LIMITATIONS

7.2.1  Limitations of the Systematic Review

The systematic review in Chapter 4 is not without limitations. Systematic review results are, at least in part, a function of the research they contain, and without good quality research, the results of the systematic review cannot be comprehensive. As discussed above, the research able to be included in Chapter 4 was of variable quality, with only a few studies of acceptable methodological rigour. It is also limited to the results of studies published before or during the period when searches were being conducted (up to August 2011). Since that time, at least two new studies have been published that appear to be within the inclusion criteria. It is possible that the inclusion of the results of these and other studies yet to be published may significantly change the findings of the review when it is updated in two years as per the Cochrane Collaboration’s requirements.

It is also important to recall that this systematic review only aims to answer the clinical question, ‘is aromatherapy effective to treat postoperative nausea and
vomiting?’ and not any questions about its effectiveness for prevention of PONV, or the suitability of this treatment in practice. Questions about aromatherapy’s effectiveness to prevent PONV are answered in other publications51 and the study in the second part of this work attempts to begin to answer the question of the suitability of using aromatherapy to treat PONV in practice.

The very limited amount of data suitable for inclusion in the meta-analyses is yet another weakness of this quantitative systematic review. Very small amounts of comparable data were found in the included studies, so that data was only able to be combined on the comparative use of rescue antiemetics in aromatherapy and non-aromatherapy groups16-19, 39, 162, and for the outcome of ‘patient satisfaction’ in groups receiving either aromatherapy or standard antiemetic treatments17, 18. Questions about aromatherapy’s effect on the length and severity of PONV in adults and children were not able to be adequately answered by this systematic review, due to the lack of suitable data to include in meta-analyses.

Studies included in the systematic review used a variety of measures and time points to assess the length and severity of participants’ nausea and vomiting. This difference in measurement meant that the reported data could not be combined to form a meta-analysis. Some of the studies also did not report enough data about their populations to enable assessment of the suitability of combining data. Meta-analyses should only be performed on data with low clinical heterogeneity.

Studies considered for inclusion in Chapter 4 were limited to randomised controlled trials and controlled clinical trials, which resulted in several studies being excluded on methodological grounds (Appendix N). It is arguable whether the inclusion of these studies would have strengthened or weakened the results. The Cochrane Collaboration’s methods focus firmly on evidence from experimental trials59, which are considered the ‘gold standard’ of research evidence197; however Pearson et al. argue that evidence should be sourced from more diverse sources and that while evidence of effectiveness from experimental trials may be more conclusive, evidence from other types of trials may also be valid and relevant to adoption in clinical practice140. When the observed trend for unblinded and non-randomised trials to show greater evidence of an effect is taken into consideration, it seems likely that this particular systematic review would not be strengthened by the addition of studies of a lower methodological quality.
7.2.2 Limitations of the Delphi Process

The Delphi process had several limitations, not the least of which was the considerable technical difficulties endured by panellists when problems were discovered with the electronic form used for them to provide their feedback on the items. Despite specialist Information Technology Services input, some panellists were unable to complete the electronic forms and alternate methods needed to be found. This meant that some feedback forms were printed and returned via the study hospital’s internal mail system or sent by fax to the researcher’s office and some participants declined to participate further.

The time commitment required by this Delphi process was quite small, with three iterative rounds and a maximum of 19 items on which panellists had to give their opinions, but the effect of the continued time commitment required should not be underestimated\textsuperscript{146}. Decreasing response rate over the course of several rounds has been identified as a common problem with Delphi processes\textsuperscript{144} and attrition was a problem for this study, with 16 original participants dwindling to 7 in the third round. It seems likely that the technical difficulties we encountered had some impact on this.

One further potential limitation was identified with the Delphi process. While the addition of the two extra items after the Delphi process was completed was based on expert advice and evidence, the final scale may have been strengthened if these items had passed through the same process as the other thirteen items in the N-BAAS.

7.2.3 Limitations of the Instrument and Survey

The modified N-BAAS instrument and the survey process had a number of significant limitations that may have impacted on the results and findings. The modified Nurses’ Beliefs About Aromatherapy Scale largely measures respondents’ beliefs about the usefulness of aromatherapy and although the second sub-scale measures beliefs about the scientific basis of aromatherapy, it could be strengthened to measure this more effectively.

In terms of the survey methods, the response rate was low, at approximately 26%, which perhaps could have been improved with personalised distribution so that each nurse and/or midwife in the relevant clinical areas received her or his own copy of the survey and could have been contacted personally with a reminder. This would have excluded those temporary ‘agency’ staff and casual (pool) staff who were not officially part of the clinical area’s staff, which was not a desirable outcome.
Personal reminders have been shown to improve response rates in surveys\textsuperscript{149} but it was not possible to give reminders due to the design of the study. An electronic version of the survey designed to be completed online may also have shown a greater response rate or a different demographic. The majority of the respondents were clinical staff, which was intentional as it was the beliefs of the staff likely to be using the intervention being sought. Responses from a greater number of management-level nurses and midwives may have given useful data about the potential for implementation of aromatherapy in practice as clinical policies and guidelines are largely driven by staff at this level.

Greater consideration of the factors influencing beliefs in aromatherapy would have enabled collection of more comprehensive data regarding staff and the environment in which they work.

7.3 IMPLICATIONS FOR CLINICAL PRACTICE

From the evidence of the systematic review, it seems isopropyl alcohol vapour inhalation could be a useful adjunct therapy for PONV, particularly when the alternative is no treatment at all. As an inexpensive, readily available therapy in most healthcare settings (in the form of injection site 'prep-pads'), isopropyl alcohol vapour inhalation could be considered for use in situations where standard antiemetics are unavailable, refused by patients, or contra-indicated. Most useful would be a treatment that can be given when standard antiemetics fail to have an effect; one that is unlikely to interact with any drugs, and does not require any set length of time between its dose and doses of antiemetic drugs.

Studies of isopropyl alcohol for PONV included in the systematic review used one 'prep-pad’ or isopropyl alcohol soaked cotton ball or gauze pad per treatment and most asked the patient to take two or three deep breaths while the pad was held close to their nose. Treatments were repeated up to three times without any adverse effects being reported. Usually, treatments were 15 minutes apart but it was unclear why that time period was chosen and no clinical rationale was given.

It could, of course, also be inferred from these results that asking a patient with nausea to take two or three deep breaths may have some therapeutic effect, with or without the aromatherapy substance. Deep breathing on its own has not been seriously examined as a therapy for PONV and yet the findings from at least one study suggest it should be\textsuperscript{162}. It is already known that supplemental oxygen can have an effect on PONV\textsuperscript{236}. Deep breathing exercises are frequently
recommended to postoperative patients in any case, so it seems there would be very little risk and some possible benefit in recommending them to nauseous patients.

There is currently no evidence to show that using peppermint oil aromatherapy reduces PONV, but there is also no evidence of its use being harmful. It has been used to treat chemotherapy-induced nausea and vomiting without serious adverse events being reported\textsuperscript{212}. Peppermint oil given orally is widely used to treat irritable bowel syndrome\textsuperscript{237} and it is an ingredient of many foods. Therefore it seems likely that there will be little clinical risk in offering this treatment if nurses or midwives wish, or in allowing patients to use it within the clinical setting, even if the evidence of an effect is incomplete.

The findings from this work have a number of implications for clinical practice, including implications for policy and clinical safety, nursing and midwifery scope of practice, and its potential to improve clinical care. While nurses and midwives may have generally positive beliefs about aromatherapy, more than belief is needed.

In terms of clinical policy and practice guidelines, while there is some literature from the United Kingdom\textsuperscript{13, 232, 238}, and some from the Australian perspective\textsuperscript{239}, including some guidance from work done in an oncology setting\textsuperscript{240}. Realising that patients were being admitted and using aromatherapy, and nurses wished to use aromatherapy to manage the pain and nausea associated with cancer treatment, and that safe practice needed to be ensured, a clinical guideline was developed\textsuperscript{240}. This policy recommends that informed consent be sought from patients before any aromatherapy\textsuperscript{240}. The number and type of essential oils and delivery modes that can be used are limited to those with evidence of effectiveness in the literature\textsuperscript{240}. Additionally, the policy mandates that all nursing interventions including aromatherapy must be recorded in the nursing notes\textsuperscript{240}. The adoption of policies such as this is an important step in facilitating the safe use of aromatherapy in practice.

Clinical safety is always a concern when new therapies are introduced into practice or existing therapies are used in a new way. Nurses and midwives have a responsibility to ensure that if they use aromatherapy it is used appropriately and safely, with due attention to any potential adverse effects\textsuperscript{13, 239}. There is also a responsibility not to ignore a potential useful therapy because it has been maligned or misunderstood in the past because it would be just as unethical not to use an effective therapy as it would be to use an ineffective one\textsuperscript{232}. 
Complementary therapies such as aromatherapy will likely fall within most nurses’ and midwives’ scope of practice as a nursing intervention. As nursing and midwifery scope of practice differs between health jurisdictions, it is difficult to make specific recommendations. Aromatherapy is not an alternative to medical care, but exists as a complement to it and as such fits with the type of nursing intervention already currently in use, such as massage, hot or cold therapies, counselling or patient teaching.

It has been recommended that essential oil use in nursing is guided by a ‘Quality Use of Medicines’ (QUM) framework. Quality use of medicines refers to the cautious selection and prescription of medicines, and their careful use and management. Dunning suggests that nurses should treat essential oils as any other medicine, subject to the same controls and safety framework, with the additional proviso that selecting and prescribing essential oils to patients comes with the responsibility to administer, document, monitor and educate in an evidence-based way. While isopropyl alcohol is, of course, not an essential oil, it seems only prudent that it be treated in the same way by nurses using it as aromatherapy to treat postoperative nausea and vomiting.

The use of aromatherapy for postoperative nausea and vomiting has the potential to improve postoperative care for a considerable proportion of patients undergoing surgical procedures. A generally positive attitude towards complementary therapies, including aromatherapy, is evident amongst many healthcare professionals. It seems likely that given the evidence contained in Chapter 4 and the beliefs expressed in the Nurses’ and Midwives Beliefs About Aromatherapy Survey, combined with institutional support through polices and clinical guidelines, that aromatherapy for postoperative nausea and vomiting can be implemented and used to improve patient care.

7.4 IMPLICATIONS FOR RESEARCH

Future research on aromatherapy for postoperative nausea and vomiting should ensure that outcomes are measured through both early and late time-points to 24 hours after surgery for a more complete assessment of its effectiveness. Further paediatric studies of isopropyl alcohol aromatherapy would enable a better evidence base for its use in this population. Well-designed and adequately powered randomised controlled trials of peppermint oil would provide evidence about this product that is currently lacking.

Future research on nurses’ and midwives beliefs about aromatherapy should design the data collection to enable predictions to be made about which nurses
and midwives, if any, are more likely to use aromatherapy in practice, which would allow education and implementation strategies to be targeted appropriately. Studies of implementing aromatherapy in practice should take into account nurses’ and midwives’ different beliefs about the usefulness and scientific basis of aromatherapy and design their studies accordingly.

Implementation studies of aromatherapy for postoperative nausea and vomiting should consider a multi-arm design, incorporating sham treatments to blind participants and assessors to group allocation, and deep breathing interventions to control for the effect that deep breathing may have on PONV outcomes. Pre-testing nurses and midwives at research sites with the N-BAAS tool may provide useful information about the potential for successful implementation. Testing a ‘bundle’ of PONV assessment and treatment interventions, with and without aromatherapy, may lead to improved patient outcomes as well as increased evidence about the effectiveness of aromatherapy for postoperative nausea and vomiting.
Bibliography


51. Carlisle J, Stevenson C. Drugs for preventing postoperative nausea and vomiting. Cochrane Database of Systematic Reviews. 2006;(3).


215. Vickers A. Why aromatherapy works (even if it doesn't) and why we need less research. The British Journal of General Practice. 2000;50(455):444.


Appendices

Appendix A
Email to invite participants to the Delphi Panel

Dear xxx,

My name is Sonia Hines and I am a Clinical Research Nurse in the Mater Nursing Research Centre. I am writing to you to ask for your help in preparing a survey for nursing staff by participating in a short expert panel, or Delphi process.

My study, "Nurses’ and midwives attitudes regarding the use of aromatherapy to treat postoperative nausea and vomiting: a pilot study" (which has approval to proceed from the Human Research Ethics Committee) involves adapting an existing survey tool, the "Beliefs About Aromatherapy Scale," to make it suitable for use by nurses in Australia.

To conduct this adaptation, I am looking to enlist the help of an expert panel of nurses who are experienced and skilled in postoperative care. The panel will be asked to rate the relevance of 20 survey questions and will have the option of suggesting the addition of extra items as well.

I understand you are extremely busy, and I thank you for reading this far; if you are unable to participate but would like to nominate a suitable colleague instead, please let me know. If you would like to participate, thank you, and I am happy to provide further details should you require them.

Sincerely,

Sonia Hines
Appendix B

Original Beliefs About Aromatherapy Tool

Please complete the following as quickly as you can. There are no right or wrong answers. Please circle the number which you think best represents the way you feel.

<table>
<thead>
<tr>
<th>Statement</th>
<th>Don't know</th>
<th>Disagree</th>
<th>Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aromatherapy is based on sound scientific principles</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aromatherapy should be seen as part of conventional medicine</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aromatherapy involves changing the body as well as the mind</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I would derive great benefit from aromatherapy</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The essential oils used in aromatherapy can change</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aromatherapy can be used to treat depression</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aromatherapy can be used to treat anxiety</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aromatherapy can be used to treat phobias</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aromatherapy can be used to treat schizophrenia</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aromatherapy can be used to treat physical ailments such as headaches backache as well as diseases</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Aromatherapy can be used to treat major illnesses such as cancer or AIDS.

To work as an aromatherapist, you do not need professional training.

Most psychological and medical research supports the claims of aromatherapy.

I would recommend aromatherapy to friends and colleagues.

Aromatherapy does not take long to work.

I would definitely consider aromatherapy treatment if I had an illness.

The most important part of aromatherapy is the massage.

The most important part of aromatherapy is the smell.

Aromatherapy makes people forget about their problems.
Appendix C
Beliefs About Aromatherapy Scale Delphi Expert Panel

Participant Information Sheet

Thank you for your interest in participating in this expert panel process; it is deeply appreciated.

**Why are we conducting this study?** The Beliefs About Aromatherapy Scale was originally devised for use with students studying Herbal Medicine and so some items might not be completely relevant to nurses. The aim of this Delphi process is for you to indicate your opinion about the relevance of each item on this scale to nursing practice, so that the final modified version of this survey can be used to gather useful data on nurses' beliefs about aromatherapy.

The final version of this survey that you help to create will be used to gather data on beliefs about aromatherapy from nursing staff in a pilot study at Mater Health Services and will form part of my Master of Applied Science (research) thesis.

**What is the "Delphi process" about?** The Delphi process is a structured communication technique designed to achieve consensus from an expert group. Experienced practitioners, such as yourself, are asked to give their opinions on a particular topic. This process uses 'iterative rounds' where the results of the group's opinion on the current version of the survey are used to create the next version. For this study, there will be three iterative rounds; which means you will be asked to give your opinion on these survey items three times. You will also receive the final version. While all participants will know which items have been thought by the group to be the most relevant, the opinions of each individual participant will only be seen by the researcher.

**What happens now?** If you consent to participating in this research, you can indicate your agreement by following these instructions and returning the form below:

- The attached form contains 19 items indicating opinions about aromatherapy. When you open the 'beliefs about aromatherapy' form, you may notice a little button that looks like this at the bottom of your screen. Please click on it to make it go away before you try to complete the survey.

- Next, please click the button on the scale which best reflects how relevant you feel each item is to nursing practice. For example:

  Item 7: "Aromatherapy can be used to treat anxiety." Do you feel this is a relevant question to ask nurses about aromatherapy? Choose the button between "irrelevant" and "very relevant" that best reflects how relevant you feel it is.

- If there are some opinions that you feel should be included on the scale that would better help us understand nurses' beliefs about using aromatherapy in practice, especially in relation to using aromatherapy for postoperative nausea and vomiting, there is space for you to suggest two extra items at the end of the scale.

- When you have completed rating the items and have added any new items you feel are needed, please save the document and return it by email.
Items that are felt by the majority of panellists to be irrelevant will be removed from the modified scale. The items felt to most relevant by the panel will appear in the final survey. *It is very important that you indicate how relevant to nursing practice you feel each item is, and not give your opinion about whether you agree or disagree with the content of the item.*

**What happens next?** Once I have received and tabulated all the responses from all panellists, I will be able to adjust the scale accordingly and send out the next version. Your prompt response is highly appreciated.

Thank you again for your participation,

Sonia Hines, RN BN MApSc (research) candidate
13. Most psychological and medical research supports the claims of aromatherapy.
14. I would recommend aromatherapy to friends and colleagues.
15. Aromatherapy does not take long to work.
16. I would definitely consider aromatherapy treatment if I had an illness.
17. The most important part of aromatherapy is the massage.
18. The most important part of aromatherapy is the smell.
19. Aromatherapy makes people forget about their problems.

Optional Additional Item 1:

Optional Additional Item 2:
Appendix D
Modified Beliefs About Aromatherapy Scale

Below are items indicating opinions about aromatherapy. They are neither right nor wrong. We are interested in learning your opinions about aromatherapy.

Please indicate your level of agreement with each of the items where 1 = *strong disagreement* and 7 = *strong agreement* with the stated opinions.

<table>
<thead>
<tr>
<th></th>
<th>Disagree</th>
<th>Don’t know</th>
<th>Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Aromatherapy is based on sound scientific principles</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Aromatherapy should be seen as part of conventional medicine</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Aromatherapy involves changing the body as well as the mind</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. The essential oils used in aromatherapy can change brain chemistry</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Aromatherapy can be used to treat depression</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Aromatherapy can be used to treat anxiety</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Aromatherapy can be used to treat phobias</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Aromatherapy can be used to treat physical ailments such as headaches, back ache as well as diseases</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. To work as an aromatherapist, you do not need professional training</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Most psychological and medical research supports the claims of aromatherapy</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Aromatherapy does not take long to work</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. Aromatherapy would benefit patients in my area of practice</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13. I would recommend aromatherapy to patients</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14. Aromatherapy can be used to treat postoperative nausea and vomiting</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15. Aromatherapy can be used in labour and delivery settings</td>
<td>1 2 3 4 5 6 7</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix E
Participant Information Sheet

Information Sheet for Participants

Project title:
Survey of registered nurses and midwives beliefs about aromatherapy.

Investigator:
Sonia Hines, RN BN MSc (candidate) Queensland University of Technology
Professor Anne Chang

About the Study:
Aromatherapy is a form of complementary and alternative medicine that involves the use of the vapours of essential oils and other substances to treat health conditions. The purpose of this questionnaire is to determine the beliefs of health care professionals regarding the use of aromatherapy within the practice area. Findings from this questionnaire will help us understand how to facilitate the introduction of evidence-based aromatherapy use in practice. Questionnaires will be distributed to registered nurses and midwives employed by Mater Health Services. This study is part of a Master of Applied Science (research) project conducted by Sonia Hines.

Your participation:
We are writing to ask for your assistance in completing a questionnaire relating to the use of aromatherapy. The attached questionnaire has been designed to find out your beliefs about aromatherapy. There are no right or wrong answers. We are interested in your opinions about using aromatherapy.

Your participation in this project is voluntary. If you do agree to participate please be assured that your responses will be anonymous. Your decision to participate will in no way impact upon your current or future relationship with Mater Health Services.

Expected benefits:
This project is not expected to benefit you directly. However, your involvement in this activity will provide vital knowledge in regard to clinicians' beliefs about the use of aromatherapy.
Risks:
There are no risks beyond the normal day to day living associated with your participation in this project.

Confidentiality:
Information that you provide will be safe-guarded and remain anonymous. The following information is important to you as a participant:

1) No identifying information such as your name will be recorded on any form.

2) Information will be kept in a locked cabinet in the Nursing Research Centre.

Results from this study may be published in a journal or presented at a conference. However, only the study hospital will be identified.

Consent to participate:
Return of the questionnaires will be taken as consent to participate in this project

Questions/further information about the project:
All participants will be provided with an opportunity to access feedback of the final results.

If you have any questions or comments on this research please contact the Nursing Research Centre on email:

sonia.hines@mater.org.au
anne.chang@mater.org.au

Concerns/complaints regarding the conduct of this project:
The study has been approved by the Mater Health Services Human Research Ethics Committee and participants may contact the Mater Research Ethics Coordinator on (07) 3163-1585, should they have any complaints about the conduct of the research, or wish to raise any concerns. The Research Ethics Coordinator may contact the Patient Representative or Hospital Ethicist at its discretion.

Your participation in this survey is very much appreciated.

Yours sincerely

Sonia Hines
Appendix F

Demographic Data Sheet

The Beliefs About Aromatherapy Survey

Thank you for agreeing to participate in our survey. It should take less than ten minutes to answer all the questions. This survey is designed to be completely anonymous. Please do not write your name or any identifying information anywhere on this form.

Demographic Data

Age:  □ 18-25  
□ 26-35  
□ 36-45  
□ 46-55  
□ 56-65  
□ 66-75

Gender:  [Blank]

Position:  □ Registered Nurse  
□ Registered Midwife  
□ Clinical Nurse  
□ Endorsed Midwife  
□ Clinical Nurse Midwife  
□ Nurse Educator  
□ Clinical Facilitator  
□ Clinical Nurse Consultant  
□ Nurse Practitioner

Years in current position:  [Blank]

Total years in nursing:  [Blank]
☐ Nurse Manager

☐ Nurse Unit Manager

☐ Other (please indicate)________________________________________

**Highest educational qualification**

**completed:**

- ☐ Hospital certificate
- ☐ Bachelor's degree
- ☐ Graduate certificate or diploma
- ☐ Masters degree
- ☐ PhD

**Current main practice focus:**

- ☐ Patient care
- ☐ Management
- ☐ Education
- ☐ Research
- ☐ Other

**Have you completed any Complementary or Alternative Therapy certifications or qualifications:**

- ☐ Yes  ☐ No

**If yes, please state which:** ________________________________
Appendix G

Mater Human Research Ethics Committee Approval

MATER HEALTH SERVICES HUMAN RESEARCH ETHICS COMMITTEE

24th March 2011

Ms Soma Hines
Nursing Research Centre
Level 1
Queens Building
Mater Health Services
Annerley Road
Woolloongabba
4102

Dear Ms Hines,

Re: Protocol Ref:166384, Nurses’ and midwives’ attitudes regarding the use of aromatherapy to treat postoperative nausea and vomiting: a pilot study

I write to advise that the Mater Health Services Human Research Ethics Committee considers the above study to meet the requirements of the National Statement on Ethical Conduct in Human Research (2007) and has granted ethical approval for your research proposal. Please accept our very best wishes for the success of this study. In all future correspondence with the Committee please quote the Mater reference number.

Documents reviewed and approved include:

- Mater Ethics Application Form
- Appendix 1A - Nurses / Midwives
- Information Sheet for Participants
- Appendix 1b - Survey Tool
- Financial Costing Summary

This approval is valid until 24th March 2014. Please note the following conditions of approval:

- Any departures from the protocol detailed in your proposal must be reported immediately to the Committee.
- If you propose a change to an approved protocol, which you consider to be minor, you are required to submit a written request for approval to the Chairperson, through the Secretary. Such requests will be considered on a case by case basis, and interim approval may be granted subject to ratification at the next meeting of the Committee.
- Where substantial changes to any approved protocol are proposed, you are required to submit a full new proposal for consideration by the Human Research Ethics Committee.
- You are required to advise the Research Ethics Coordinator immediately of any complaints made, or expressions of concern raised, in relation to the study, or if any serious or unexpected adverse events occur.
- Under the NHMRC National Statement on Ethical Conduct in Research Involving Humans, research ethics committees are responsible for monitoring approved research to ensure continued compliance with ethical standards, and to determine the method of monitoring appropriate to each project. You are required to provide written reports on the progress of the approved project annually, the first report being due on 24th March 2012 and finally on completion of the project.
project. (The Progress Report is located at [http://www.mater.org.au/Research/Human-Research-Ethics-Committee.aspx](http://www.mater.org.au/Research/Human-Research-Ethics-Committee.aspx) or can be accessed through the Mater Intranet. Applications, Research Register and under the project name or alternatively can be emailed to you). Please inform the Committee of publications, presentations at Conferences, education and quality improvement outcomes from this study. The Committee may also choose to conduct an interim audit of your research.

- Please be aware that all study procedures including follow up of participants and data analysis should be completed within the approval time frame or an extension should be requested.

Please contact the Executive Director in the participating hospital/hospitals prior to commencing of the study. To access medical records for the purpose of this study, please provide a copy of the approval letter to the Corporate Health Information Manager. I would also be grateful if you could confirm the date of commencement. (All correspondence should be directed to the Mater Research Ethics Coordinator.)

Yours sincerely

Dr Andrew Cowden
Chairperson
Mater Health Services Human Research Ethics Committee
Appendix H

Mater Human Research Ethics Committee Amendment Approval

MATER HEALTH SERVICES HUMAN RESEARCH ETHICS COMMITTEE

9th December 2011

Ms Sosla Hines
Nursing Research Centre
Level 1
Quarterm Building
Mater Health Services

Dear Ms Hines,

Re: Protocol Ref: U651A Nurses' attitudes towards the use of aromatherapy to treat postoperative nausea and vomiting: a pilot study

I write to advise that the Mater Health Services Human Research Ethics Committee has granted ethical approval for the proposed amendments for the above study.

Documents reviewed and approved include:

- Letter dated 9th February 2011 outlining amendment request
- Updated tool - Beliefs about Aromatherapy Scale for use in Phase 2

You are reminded that this letter constitutes ethical approval only. You may also need to consult with the Research Governance Office to ensure the amendments comply with the existing authorisation that has been obtained.

Please accept our best wishes for the remainder of the study and should you have any queries, please do not hesitate to contact the Research Ethics Secretariat on 3153 1990. If all future correspondence with the Committee please quote the Mater reference number.

Yours sincerely,

[Signature]

A/Prof Andrew Crowden
Chairperson
Mater Health Services Human Research Ethics Committee
Appendix I
Administrative Ethics Approval, QUT

Dear Ms Sonia Hines

Project Title:
Nurses' and midwives attitudes regarding the use of aromatherapy to treat postoperative nausea and vomiting: a pilot study

Approval Number: 1100000420
Clearance Until: 2/03/2014
Ethics Category: Human

This email is to advise that your application has been reviewed by the Chair, University Human Research Ethics Committee and confirmed as meeting the requirements of the National Statement on Ethical Conduct in Human Research. We note ethics clearance has already been obtained from another institution.

Whilst the data collection of your project has received ethical clearance, the decision to commence and authority to commence may be dependent on factors beyond the remit of the ethics review process. For example, your research may need ethics clearance from other organisations or permissions from other organisations to access staff. Therefore the proposed data collection should not commence until you have satisfied these requirements.

If you require a formal approval certificate, please respond via reply email and one will be issued.

This project has been awarded ethical clearance until 2/03/2014 and a progress report must be submitted for an active ethical clearance at least once every twelve months. Researchers who fail to submit an appropriate progress report may have their ethical clearance revoked and/or the ethical clearances of other projects suspended. When your project has been completed please advise us by email at your earliest convenience.
For variations, please ensure that approval has been sought from the lead university before completing and submit the QUT online variation form:

http://www.research.qut.edu.au/ethics/forms/hum/var/variation.jsp
**Appendix J**

**Search Strategy**

**Search Strategy for MEDLINE (via Ovid) (1966 to August 2011)**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>randomised controlled trial.pt.</td>
</tr>
<tr>
<td>2</td>
<td>aromatherap* OR complementary OR ginger OR peppermint OR isopropyl alcohol.mp</td>
</tr>
<tr>
<td>3</td>
<td>controlled clinical trial.pt.</td>
</tr>
<tr>
<td>4</td>
<td>randomised.ab.</td>
</tr>
<tr>
<td>5</td>
<td>vomit* OR nausea* OR PONV.mp</td>
</tr>
<tr>
<td>6</td>
<td>placebo.ab.</td>
</tr>
<tr>
<td>7</td>
<td>drug therapy.fs.</td>
</tr>
<tr>
<td>8</td>
<td>randomly.ab.</td>
</tr>
<tr>
<td>9</td>
<td>trial.ab.</td>
</tr>
<tr>
<td>10</td>
<td>groups.ab.</td>
</tr>
<tr>
<td>11</td>
<td>1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10</td>
</tr>
<tr>
<td>12</td>
<td>humans.sh.</td>
</tr>
<tr>
<td>13</td>
<td>11 and 12</td>
</tr>
<tr>
<td>14</td>
<td>(exp postoperative nausea and vomiting/)</td>
</tr>
<tr>
<td>15</td>
<td>(postoperative adj6 nausea adj6 vomiting).mp</td>
</tr>
<tr>
<td>16</td>
<td>(postoperative adj6 care).mp</td>
</tr>
<tr>
<td>17</td>
<td>(recovery adj6 room).mp</td>
</tr>
<tr>
<td>18</td>
<td>(anesthesia adj6 recovery adj6 period).mp</td>
</tr>
<tr>
<td>19</td>
<td>14 or 15 or 16 or 17 or 18</td>
</tr>
<tr>
<td>20</td>
<td>(exp aromatherapy/)</td>
</tr>
<tr>
<td>21</td>
<td>(holistic adj6 health).mp</td>
</tr>
<tr>
<td>22</td>
<td>(medicine adj6 traditional).mp</td>
</tr>
<tr>
<td>23</td>
<td>(naturopath$).mp</td>
</tr>
<tr>
<td>24</td>
<td>(phytetherap$).mp</td>
</tr>
<tr>
<td>25</td>
<td>(medicinal adj6 plant$).mp</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>26</td>
<td>(ginger).mp</td>
</tr>
<tr>
<td>27</td>
<td>(Mentha adj6 piperita).mp</td>
</tr>
<tr>
<td>28</td>
<td>20 or 21 or 22 or 23 or 24 or 25 or 26 or 27</td>
</tr>
<tr>
<td>29</td>
<td>13 and 19 and 28</td>
</tr>
<tr>
<td>30</td>
<td>humans.sh.</td>
</tr>
<tr>
<td>31</td>
<td>29 and 30</td>
</tr>
</tbody>
</table>
# Appendix K

## Verification of Study Eligibility Form

<table>
<thead>
<tr>
<th>AUTHOR AND YEAR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>JOURNAL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TITLE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NAME/CODE OF REVIEWER</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Setting: Acute hospital or surgical day facility</th>
<th>Yes   No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Population: Adults or children having surgical procedures under anaesthesia</th>
<th>Yes   No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Intervention: Experimental group patients are receiving aromatherapy to treat PONV</th>
<th>Yes   No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Study Design: RCT or CCT</th>
<th>Yes   No</th>
</tr>
</thead>
</table>

**IF YOU HAVE NOT ANSWERED YES TO ALL OF THE ABOVE QUESTIONS, YOU SHOULD EXCLUDE THE STUDY. IF YOU ANSWERED YES TO ALL, PLEASE CONTINUE.**

<table>
<thead>
<tr>
<th>Language: Does the study require translation before it can be appraised?</th>
<th>Yes   No</th>
</tr>
</thead>
</table>

**If yes, please arrange for translation before proceeding**

**PLEASE RECORD ALL STUDY DETAILS AS PER THE DATA MANAGEMENT FLOW SHEET**
## Appendix L

Data Extraction Form

<table>
<thead>
<tr>
<th>AUTHOR AND YEAR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>JOURNAL/SOURCE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TITLE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>INITIALS OF REVIEWER:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>STUDY METHOD</th>
<th>RCT ?</th>
<th>Quasi RCT ?</th>
<th>CCT ?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PARTICIPANT</th>
<th>Group</th>
<th>Group</th>
<th>Group</th>
<th>Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number in each group</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean age and range</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Population</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Setting</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procedure/s</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participants excluded in selection criteria</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participants who left study and reasons why</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>INTERVENTION</th>
<th>Group</th>
<th>Group</th>
<th>Group</th>
<th>Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aromatherapy type</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Method of administration</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dose (if stated)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OUTCOMES</td>
<td>Group</td>
<td>Group</td>
<td>Group</td>
<td>Group</td>
</tr>
<tr>
<td>------------------------------</td>
<td>-------</td>
<td>-------</td>
<td>-------</td>
<td>-------</td>
</tr>
<tr>
<td>Nausea (severity score?)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vomiting (severity score?)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adverse reactions</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rescue antiemetics used</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Author’s Conclusion</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Appendix M

Characteristics of Included Studies

### Anderson 2004

| **Methods** | Randomised controlled trial of peppermint oil, isopropyl alcohol or normal saline aromatherapy to treat postoperative nausea and vomiting.  
Setting: Postanaesthesia care unit (PACU) acute hospital, USA. |
|-------------|---------------------------------------------------------------------------------------------------------------------------------|
| **Participants** | 33 patients aged 18 years+ having surgery under general or regional anaesthesia, or deep IV sedation, who reported nausea in postanaesthesia care unit. Treatment groups did not differ in the percentage having general anaesthesia, the type of surgery, age or sex distribution.  
Exclusions: patients who were unable to give informed consent; patients who did not require anaesthesia services. |
| **Interventions** | On the patient's spontaneous report of postoperative nausea, they were instructed to take three slow deep breaths to inhale the vapours from a pre-prepared gauze pad soaked with either peppermint oil, isopropyl alcohol or normal saline placebo held directly under their nostrils. After 2 minutes the patient was asked to rate their nausea by VAS and given the choice to continue aromatherapy or have standard IV antiemetics. At 5 minutes post the initial treatment, the patient was again asked to rate their nausea and if they would like to continue aromatherapy or have standard IV antiemetics. |
| **Outcomes** | 1. Severity of nausea as measured on 100 mm VAS at 2 minutes and 5 minutes after treatment. Visual analogue scale from 'no nausea' to 'worst possible nausea'.  
2. Choosing to use 'rescue' antiemetics. |
3. Satisfaction with management of nausea, as measured by 100 mm VAS with range from 0 = extremely dissatisfied to 100 = fully satisfied.

**Notes**

Possible lack of accuracy with some participants self-recording data in PACU if they had poor or blurred vision. Authors Lynn Anderson and Dr Jeffrey Gross emailed to request further information on group sizes, which was supplied by Dr Gross.

### Risk of bias table

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>&quot;group assignments were made in a randomised, double-blind fashion&quot;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Comment: probably done. Nurses administering treatment were unaware of contents of each package of treatment materials. Patients who had consented to participate entered study when they spontaneously reported nausea.</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>&quot;A random number generator determined the contents of each serially numbered bag.&quot;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&quot;...prepared by an individual not otherwise involved in the study...&quot;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Data &quot;analysed by investigator unaware of treatment allocation&quot;.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Comment: probably done</td>
</tr>
<tr>
<td>Blinding (performance bias and</td>
<td>Unclear risk</td>
<td>Staff administering treatment blinded by use</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
of "lightly scented" surgical masks. However patients were self-reporting subjective assessment of nausea and were not blinded.

Comment: Due to the strong aroma of the peppermint oil, it would be impossible to blind the patients receiving this to their allocation once treatment commenced. Probably not done.

|Incomplete outcome data (attrition bias) | Low risk | Comment: outcomes reported for all participants. |
|Selective reporting (reporting bias)    | Unclear risk | Comment: results reported for all stated outcomes, however original study protocol not available. |
|Other bias                              | Low risk | Comment: study appears to be free of other sources of bias. |

Cotton 2007

**Methods**

Prospective randomised study of isopropyl alcohol inhalation as compared to IV ondansetron for PONV. Replication of study: Winston 2003

Setting: PACU/same day surgery unit, USA.

**Participants**

100 women aged 18-65 who were scheduled for laparoscopic same-day surgery (ASA physical status I, II or III) exclusions: patients who had recent upper respiratory tract infections, inability or impaired ability to breathe through the nose, or history of hypersensitivity to IPA, 5HT3 antagonists, promethazine or any
other anaesthesia protocol medication, had used an antiemetic within 24 hours of surgery, were pregnant or breastfeeding, had history of inner ear pathology, motion sickness or migraine headaches or were taking disulfram, cefoperazone, or metronidazole.

<table>
<thead>
<tr>
<th>Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comparison of inhaled isopropyl alcohol to ondansetron for treatment of PONV.</td>
</tr>
<tr>
<td>Ondansetron (control) group: nausea treated with ondansetron 4 mg IV every 15 minutes to a maximum 8 mg dose. Time, dose and VNRS score recorded.</td>
</tr>
<tr>
<td>IPA (experimental) group: nausea treated by holding a folded alcohol pad approximately 1/2 inch from the participant's nares and instructing them to take 3 deep breaths in and out through the nose. Treatments given every 5 minutes up to a total of 3 administrations.</td>
</tr>
<tr>
<td>Breakthrough PONV was treated with promethazine suppositories for both groups.</td>
</tr>
<tr>
<td>Participants were also given supplies of IPA and promethazine to use as needed at home after discharge and asked to record any occurrences of PONV with a data collection tool provided by the researchers.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time to reduction in nausea score as measured by Verbal Numeric Rating Scale (VRNS) (range 0-10 where 0 = no nausea and 10 = worst imaginable nausea). Collected for baseline at preop, then immediately postop in PACU and at any time the participant complained of nausea. Additionally, participants who complained of nausea were assessed every 5 minutes following treatment for 30 minutes and then every 15 minutes until discharge from PACU.</td>
</tr>
<tr>
<td>Participants also reported data on PONV for the 24 hours post-discharge as well rating their anaesthesia experience overall.</td>
</tr>
</tbody>
</table>
Author, Joseph Pellegrini contacted for further data. Some was provided however due to data corruption problems not all requested data was available.

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>&quot;patient was randomly assigned to the control group or the experimental group by using a computer-generated random numbers program.&quot;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Comment: done.</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>&quot;Block randomisation was used for all of the studies using a computer generated randomisation program done by an independent party (myself) who was not involved in the data collection&quot; (emailed author response)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Comment: done.</td>
</tr>
<tr>
<td>Blinding (performance bias and detection bias)</td>
<td>Unclear risk</td>
<td>Comment: no information given regarding blinding. Does not appear to have been done.</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>28 participants &quot;disenrolled due to protocol violations&quot;: 12 from control group who were given IPA postoperatively; 6 from experimental group given other antiemetics in PACU before IPA; and 10 who lost their IPA or promethazine following</td>
</tr>
</tbody>
</table>
Methods
Randomised controlled trial of ISO vs normal saline placebo for treatment of PONV.
Setting: postoperative care unit, acute hospital, Iran.

Participants
82 consecutive patients randomised into experimental and control groups. No age data or demographic except 48 female/34 male.

Interventions
2 sniffs of ISO (treatment) or 2 sniffs normal saline (control) (on reporting symptoms?) and re-treated at 5 minutes if necessary. Pts who did not respond the 2nd time received metoclopramide injection.

Outcomes
Response to treatment/cessation of symptoms, recurrence of symptoms, use of rescue antiemetics.

Notes
Attempted to contact author, Dr H Kamalipour, via email however no response received.

Risk of bias table

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>Comment: original study protocol unavailable. Results reported for all stated outcomes.</td>
</tr>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>Comment: study appears to be free of other sources of bias.</td>
</tr>
</tbody>
</table>

Appendices 151
Langevin 1997

**Methods**

Double-blinded crossover clinical trial/pilot study.

Setting: acute hospital, USA.

**Participants**

15 consecutive patients in PACU who complained of nausea or vomiting after elective surgery.

**Interventions**

Either 0.5 ml saline or 0.5 ml isopropyl alcohol on a cotton ball (according to random sequence) was held under participants' noses and the participant was instructed to sniff twice. If symptoms recurred, the test agents were re-administered in random sequence. When neither test agent was effective, standard antiemetics were given and the PONV assessed every 5 minutes until participant left PACU.

**Outcomes**

Severity of PONV as assessed with VAS.
<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation</td>
<td>Unclear risk</td>
<td>&quot;the test agents were readministered in the randomised sequence&quot;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Comment: no information on how this sequence was generated.</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Comment: no information reported on who conducted the allocation and how.</td>
</tr>
<tr>
<td>Blinding (performance bias and detection bias)</td>
<td>Unclear risk</td>
<td>&quot;We designed a randomised double-blinded study...&quot; &quot;Nurses who administered the test therapy were blinded to group assignment by applying an ISO-soaked Band-Aid under their noses while another person applied the test agent to a cotton ball, which was attached to a sponge stick.&quot;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Comment: participants would not have been blinded to the treatment due to the distinctive odour of the isopropyl alcohol. Unclear where</td>
</tr>
<tr>
<td>Bias</td>
<td>Risk</td>
<td>Comment</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>-----------------</td>
<td>-------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Unclear risk</td>
<td>Comment: original study protocol not available.</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>Comment: data reported for all participants, no apparent losses to follow-up.</td>
</tr>
<tr>
<td>Other bias</td>
<td>Unclear risk</td>
<td>Comment: minimal data reported in this publication.</td>
</tr>
</tbody>
</table>

Merritt 2002

**Methods**

Controlled clinical trial of isopropyl alcohol inhalation for treatment of PONV.

Setting: acute hospital, USA.

**Participants**

111 adults having surgery (40 with nausea were evaluated for study). Age range: 19-80 years; mean age = 43. Types of surgery included intra-abdominal (29.7%), orthopaedic/extremity (23.4%), perineal (19.8%) neuro-skeletal (10.8%), extrathoracic (6.3%) eyes/ears/nose/throat (6.3%), neck (3.6%).

Of 40 patients evaluated for study, 21 received IPA and 18 were controls. 1 patient entered into the study had their PONV resolve spontaneously.

Inclusion criteria were (a) requirements for general anaesthesia, (b) ability to breathe through nose before and after procedure, (c) minimum of 18 years of age, (d) American Society of Anesthesiologists (ASA) physical status of I, II, or III, and (e) ability to read and write English.

Exclusion criteria were (a) allergy to IPA, (b) alcohol abuse, (c) no recent history of nausea or vomiting within the last 8 hours, (d) no recent intake of cefoperazone,
Antabuse, or metronidazole, (e) ability to communicate in recovery room, (f) regional anaesthesia, and (g) monitored anaesthesia care.

Interventions

Isopropyl alcohol inhalation for treatment of PONV. "If nausea or vomiting was present in control participants, an appropriate antiemetic was given. Experimental participants were given IPA via nasal inhalation using standard hospital alcohol pads. The participant was instructed to take three deep sniffs with the pad one inch from the nose. This was repeated every five minutes for three doses or until nausea and vomiting was relieved. If nausea and vomiting continued after three doses of IPA, then an intravenous drug was given."

Outcomes

Severity of PONV as measured by a descriptive ordinal scale (DOS) from "0 to 10, with 0 being no nausea or vomiting and 10 being the worst nausea and vomiting they could imagine."

Cost of treatment in USD.

Notes

Antiemetic prophylaxis was given to patients in both groups.

Risk of bias table

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>High risk</td>
<td>&quot;Group assignment was alternated by day: experimental one day and control the next.&quot;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Comment: study is controlled clinical trial.</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Comment: allocators and caregivers appear to have been aware of the</td>
</tr>
</tbody>
</table>
Blinding (performance bias and detection bias) | Low risk | “Participants were blinded to which treatment they were to receive.” Comment: probably done.

Incomplete outcome data (attrition bias) | Unclear risk | Comment: original study protocol unavailable. Stated outcomes were all addressed in report.

Selective reporting (reporting bias) | Unclear risk | Comment: no apparent loss to follow-up. No P values reported for main findings of pre and post-test DOS, though P value for cost differences reported.

Other bias | Unclear risk | "Only 40 of the 111 participants recruited had PONV. This is explained by aggressive prophylactic treatment at the study facility where only 7 (6.3%) of 111 participants did not receive prophylactic medication and none of these 7 participants had PONV. Additionally, the researchers speculate that pain may have been a confounding factor in accurate assessment on the DOS.” Comment: several possible confounders.

Pellegrini 2009

| Methods | Randomised controlled trial comparing 70% allocation. |
isopropyl alcohol inhalation to promethazine to treat breakthrough nausea in surgical patients at high risk of PONV.

Setting: day hospital, USA.

| Participants | 85 surgical patients scheduled for general anaesthesia of more than 60 minutes’ duration and having 2 of the 4 individual risk factors for PONV, (female sex, nonsmoker, history of PONV or motion sickness) (IPA group, 42; promethazine group, 43).
Excluded: recent upper respiratory infection; documented allergy to IPA, ondansetron, promethazine, or metoclopramide; antiemetic or psychoactive drug use within 24 hours; inability to breathe through the nose; pregnancy; history of inner ear pathology; and/or taking disulfiram, cefoperazone, or metronidazole. |
| Interventions | Control group: 12.5 to 25 mg IV promethazine for complaints of PONV in the postanaesthesia care unit (PACU) and same-day surgery unit (SDSU) and by promethazine suppository self-administration following discharge to home.
Experimental group: administration of inhaled 70% IPA. |
| Outcomes | Nausea, measured by Verbal Numeric Rating Scale (VNRS) (0-10, 0 = no nausea 10 = worst imaginable nausea)
Incidence of nausea events in PACU, SDSU or at home (number)
Doses of promethazine required as rescue antiemetic (number)
Promethazine requirements in PACU, SDSU or at home (mg)
Time in minutes to 50% reduction of nausea scores
Participant satisfaction |
All participants received antiemetic prophylaxis prior to surgery. Author J Pellegrini emailed to request numeric data for results published in graph form. Data received. Other clarifications requested and some were received.

<table>
<thead>
<tr>
<th>Risk of bias table</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bias</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Random sequence generation (selection bias)</td>
<td><strong>Low risk</strong></td>
<td>&quot;All subjects were then randomly assigned using a computer-generated random numbers process into a control or an experimental group.&quot; Comment: probably done.</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td><strong>Low risk</strong></td>
<td>&quot;Block randomisation was used for all of the studies using a computer generated randomisation program done by an independent party (myself) who was not involved in the data collection.&quot; (emailed author response) Comment: probably done.</td>
</tr>
<tr>
<td>Blinding (performance bias and detection bias)</td>
<td><strong>Unclear risk</strong></td>
<td>Comment: no data on blinding. It appears that participants and assessors were aware of group allocations during study.</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td><strong>Low risk</strong></td>
<td>&quot;A total of 96 subjects were enrolled, but 11 subjects were withdrawn, leaving a total of 85 subjects (IPA group, 42; promethazine group, 43)&quot;</td>
</tr>
</tbody>
</table>
whose data would be included in the final analysis. Reasons for withdrawal included 4 subjects who received additional antiemetics intraoperatively (2 in each group), 1 subject inadvertently enrolled despite being scheduled for a nasal surgical procedure (IPA group), and 6 subjects who required postoperative inpatient hospitalization for reasons unrelated to PONV (3 in each group)."
Comment: probably done.

<table>
<thead>
<tr>
<th>Selective reporting (reporting bias)</th>
<th>Unclear risk</th>
<th>Comment: all outcomes stated in the article have data reported, however original study protocol is not available.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other bias</td>
<td>Low risk</td>
<td>Comment: no other sources of bias apparent.</td>
</tr>
</tbody>
</table>

Tate 1997

**Methods**

<p>| |</p>
<table>
<thead>
<tr>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Three-arm controlled clinical trial of peppermint oil inhalations, peppermint essence inhalations (placebo) and no treatment (control) to treat PONV in women.</td>
</tr>
<tr>
<td>Setting: acute hospital, UK.</td>
</tr>
</tbody>
</table>

**Participants**

<p>| |</p>
<table>
<thead>
<tr>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>18 women undergoing major gynaecological surgery. Mean weight group 1: 152lb; group 2: 139.5lb; group 3: 144.2lb. Mean height group 1: 64.2in; group 2: 62.5in; group 3: 64.3in. Mean age group 1: 54 years; group 2: 43.2 years; group 3: 45.5 years. Participants were</td>
</tr>
</tbody>
</table>

assessed as having no significant differences in personal characteristics, past medical history or preoperative anxiety levels. There were no statistically significant differences in preoperative fasting times, anaesthetic and recovery times or postoperative fasting times. Five of the experimental group had intra-abdominal surgery, compared with three in each of the other two groups.

### Interventions

Participants were given bottles of their assigned substance postoperatively and instructed to inhale the vapours from the bottle whenever they felt nauseous.

### Outcomes

Self-reported nausea as measured by VAS of 0-4 where 0 = "not experiencing any nausea" and 4 = "about to vomit" reported as the average score per person per day.

- Cost of treatment in GBP.
- Patient satisfaction with treatment, reported narratively.

### Notes

Participants may or may not have received standard antiemetics in PACU. Author Sylvina Tate supplied some extra data on group allocation methods.

## Risk of bias table

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
</table>
| Random sequence generation (selection bias) | Unclear risk ▼    | "The subjects were assigned to one of three groups."  
Comment: Author states that participants were "randomly assigned" to ward areas. |
<p>| Allocation concealment (selection bias) | Unclear risk ▼    | Comment: no information reported regarding concealment.                               |</p>
<table>
<thead>
<tr>
<th>Bias Type</th>
<th>Risk Level</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blinding (performance bias and detection bias)</td>
<td>Low risk</td>
<td>Comment: use of peppermint essence as placebo blinded experimental and placebo group patients to treatment allocation.</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Unclear risk</td>
<td>Comment: no mention of patients lost to follow-up, however group numbers are not reported. (Group numbers clarified by author via email)</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>High risk</td>
<td>Comment: trialists did not provide measure of statistical significance or measures of variance for daily average nausea scores, even though they state 'statistically significant difference in the amount of self-reported nausea between the placebo and experimental groups.</td>
</tr>
<tr>
<td>Other bias</td>
<td>Unclear risk</td>
<td>Comment: due to study design, entirely possible there was some demand-characteristic effect on patient self-reporting of results. However, experimental group received 'on average, slightly less' postoperative antiemetics and more postoperative opioids than placebo group, which would tend to indicate evidence of an effect.</td>
</tr>
</tbody>
</table>

**Wang 1999**

**Methods**

Double-blind randomised controlled study of isopropyl alcohol as a treatment for...
PONV. "When any episode of vomiting or nausea occurred, patients were randomised, using a random number table to receive a cotton ball soaked with ISO or saline placed under the patient’s nose by the nursing staff. The patient was instructed to sniff twice by a nurse who was blind to group assignment. It should be emphasized that the nursing staffs were instructed not to smell the content of cotton ball and to hold it away from themselves when administering to patient.

If the severity of nausea or vomiting improved after a single treatment, a VAS assessment of nausea was obtained every 5 minutes until the patient was discharged or PONV symptoms recurred. Improvement of nausea was defined as a decrease of at least 40% in initial VAS score, and improvement of vomiting was defined as no further episodes of vomiting. If, after treatment, severity of nausea did not improve or retching/vomiting persisted, a second treatment with the same agent was given. Treatment sequences were repeated for a maximum of three times in a 15-minute period. When severity of either nausea or vomiting failed to improve despite three treatments, intravenous (IV) ondansetron 0.1 mg/kg (maximum 4 mg) was administered. If symptoms persisted, a second dose of ondansetron was administered. For patients who failed to improved after two ondansetron doses (maximum dose: 8 mg), other IV antiemetic medications (i.e., 200 mg/kg of metoclopramide; 10 mg/kg droperidol) were given."

Setting: acute paediatric day surgery centre.

**Participants**

91 children aged 6-16 years having surgery under general anaesthesia. ASA physical status I and II. Of these, 39 developed PONV and were enrolled into treatment or control groups. Treatment n = 20. Control n = 19. No significant differences in
demographic data across groups.
Exclusions: children with a history of chronic illness or developmental delay.

**Interventions**
Inhalations of isopropyl alcohol or saline placebo. Intervention repeated up to three times. IV ondansetron was used as 'rescue therapy' if PONV continued.

**Outcomes**
1. Severity of nausea and vomiting as measured by 100 mm VAS with a range of 0 = no nausea to 100 = extreme nausea.
2. Use of rescue antiemetics as measured by drug and number of doses.

**Notes**
Study author, Dr Shu-Ming Wang contacted for any further data, however due to the age of the study there was none available.

---

**Risk of bias table**

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation</td>
<td>Low risk</td>
<td>&quot;If any episode of vomiting or nausea occurred, patients were randomised, using a random number table to receive a cotton ball soaked with ISO or saline placed under the patient’s nose by the nursing staff.&quot; Comment: probably done.</td>
</tr>
<tr>
<td>Allocation concealment</td>
<td>Unclear risk</td>
<td>Comment: no data on who conducted the allocation and any degree of separation from the conduct of the study.</td>
</tr>
<tr>
<td>Blinding (performance bias and)</td>
<td>Low risk</td>
<td>&quot;The patient was instructed to sniff twice&quot;</td>
</tr>
<tr>
<td>Bias Type</td>
<td>Risk Level</td>
<td>Comment</td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>------------</td>
<td>--------------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| Detection bias                                  |            | by a nurse who was blind to group assignment. It should be emphasized that the nursing staffs were instructed not to smell the content of cotton ball and to hold it away from themselves when administering to patient."
| Comment: probably done.                        |            |                                                                                             |
| Incomplete outcome data (attrition bias)       | Low risk   | Comment: data reported for all participants. No apparent losses to follow-up.               |
| Selective reporting (reporting bias)           | Unclear risk | Comment: original study protocol not available. All stated outcomes reported.               |
| Other bias                                     | Low risk   | Comment: no other sources of bias apparent.                                                 |

**Winston 2003**

**Methods**

Randomised controlled trial of isopropyl alcohol for treatment of PONV. Participants were randomised to receive either isopropyl alcohol inhalations, or 4 mg ondansetron.

Setting: same day surgery centre, USA.

**Participants**

100 women aged 18-65 who were scheduled for diagnostic laparoscopy, operative laparoscopy or laparoscopic bilateral tubal occlusion (ASA physical status I, II or III) in a day surgery unit.

Exclusions: inability or impaired ability to breathe through the nose, or history of sensitivity to IPA or ondansetron, had used an antiemetic within 24 hours of surgery, pregnant or breastfeeding, reported existing nausea, history of significant PONV.
resistant to antiemetics, using disulfram or had a history of alcoholism.

**Interventions**

Comparison of inhaled 70% isopropyl alcohol to ondansetron for treatment of PONV.

Ondansetron (control) group: at first request for treatment participants in this group received IV ondansetron 4 mg, repeated once in 15 minutes if required.

70% IPA (experimental) group: a standard alcohol prep-pad was held under the participant's nose and she was instructed to take 3 consecutive deep breaths through the nose.

Nausea score collected for baseline at preop, then immediately postop in PACU and at any time the participant complained of nausea. Additionally, participants who complained of nausea were assessed every 5 minutes following treatment for 30 minutes and then every 15 minutes until discharge from PACU.

**Outcomes**

1. Nausea score as measured by Verbal Numeric Rating Scale (VRNS) (range 0-10 where 0 = no nausea and 10 = worst imaginable nausea)
2. Number of emetic events, defined as episodes of nausea or vomiting more than one minute apart
3. Time to reduction of PONV in minutes
4. Cost
5. Patient satisfaction with anaesthesia care

**Notes**

This study was replicated by Cotton 2007 with the number and frequency of IPA inhalations increased. Author J Pellegrini provided additional data via email.

**Risk of bias table**

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors' judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
</table>
### Random sequence generation (selection bias)

- Low risk

> "subjects were randomly assigned to receive inhaled 70% IPA (experimental group) or IV ondansetron (control group) for the treatment of PON" "despite the use of block randomisation"

Comment: author states via email that randomisation was conducted using a computer generated random numbers table.

### Allocation concealment (selection bias)

- Low risk

> "Block randomisation was used for all of the studies using a computer generated randomisation program done by an independent party (myself) who was not involved in the data collection."

Comment: probably done.

### Blinding (performance bias and detection bias)

- High risk

> "...this did not allow us to blind the study intervention."

Comment: it appears that no blinding of participants or caregivers was done.

### Incomplete outcome data (attrition bias)

- Low risk

Comment: it appears that data was reported for all participants, no evidence of exclusions or attrition.

### Selective reporting (reporting bias)

- Unclear risk

Comment: original study protocol unavailable. Despite stating collection of data on patient satisfaction with anaesthetic experience,
no results for this were reported, however this data was made available by an author via email.

| Other bias | Low risk | Comment: no other sources of bias apparent. |
Appendix N
Characteristics of Excluded Studies

Apariman 2006

<table>
<thead>
<tr>
<th>Reason for exclusion</th>
<th>Prevention of PONV, not treatment.</th>
</tr>
</thead>
</table>

Apfel 2001

<table>
<thead>
<tr>
<th>Reason for exclusion</th>
<th>Not RCT/CCT. Not aromatherapy.</th>
</tr>
</thead>
</table>

Arfeen 1995

<table>
<thead>
<tr>
<th>Reason for exclusion</th>
<th>Prevention of PONV, not treatment.</th>
</tr>
</thead>
</table>

Betz 2005

<table>
<thead>
<tr>
<th>Reason for exclusion</th>
<th>Not RCT/CCT.</th>
</tr>
</thead>
</table>

Bone 1990

<table>
<thead>
<tr>
<th>Reason for exclusion</th>
<th>Prevention of PONV, not treatment.</th>
</tr>
</thead>
</table>

Buckle 1999

<table>
<thead>
<tr>
<th>Reason for exclusion</th>
<th>Not RCT/CCT.</th>
</tr>
</thead>
</table>

Chaiyakunapruk 2006

<table>
<thead>
<tr>
<th>Reason for exclusion</th>
<th>Prevention of PONV, not treatment.</th>
</tr>
</thead>
</table>

Chiravalle 2005

<table>
<thead>
<tr>
<th>Reason for exclusion</th>
<th>Not RCT/CCT.</th>
</tr>
</thead>
</table>

Chrubasik 2005

<table>
<thead>
<tr>
<th>Reason for exclusion</th>
<th>Not RCT/CCT.</th>
</tr>
</thead>
</table>

Couture 2006

<table>
<thead>
<tr>
<th>Reason for exclusion</th>
<th>Prevention of PONV, not treatment.</th>
</tr>
</thead>
</table>

DePradier 2006

<table>
<thead>
<tr>
<th>Reason for exclusion</th>
<th>Not RCT/CCT.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Author</td>
<td>Year</td>
</tr>
<tr>
<td>-----------------</td>
<td>--------</td>
</tr>
<tr>
<td>Eberhart</td>
<td>2006</td>
</tr>
<tr>
<td>Ekenberg</td>
<td>2007</td>
</tr>
<tr>
<td>Ernst</td>
<td>2000</td>
</tr>
<tr>
<td>Fujii</td>
<td>2008</td>
</tr>
<tr>
<td>Geiger</td>
<td>2005</td>
</tr>
<tr>
<td>Golembiewski</td>
<td>2005</td>
</tr>
<tr>
<td>Keifer</td>
<td>2007</td>
</tr>
<tr>
<td>Kim</td>
<td>2006</td>
</tr>
<tr>
<td>Kim</td>
<td>2007</td>
</tr>
<tr>
<td>King</td>
<td>2009</td>
</tr>
<tr>
<td>Koretz</td>
<td>2004</td>
</tr>
<tr>
<td>Mamaril</td>
<td>2006</td>
</tr>
<tr>
<td>Study</td>
<td>Reason for exclusion</td>
</tr>
<tr>
<td>---------------------</td>
<td>------------------------------------------</td>
</tr>
<tr>
<td>Morin 2004</td>
<td>Not RCT/CCT.</td>
</tr>
<tr>
<td>Nale 2007</td>
<td>Not RCT/CCT.</td>
</tr>
<tr>
<td>Pongrojpaw 2003</td>
<td>Not RCT/CCT.</td>
</tr>
<tr>
<td>Spencer 2004</td>
<td>Not RCT/CCT.</td>
</tr>
<tr>
<td>Tavlan 2006</td>
<td>Not RCT/CCT.</td>
</tr>
<tr>
<td>Visaylaputra 1998</td>
<td>Not RCT/CCT.</td>
</tr>
<tr>
<td></td>
<td>Prevention of PONV, not treatment.</td>
</tr>
</tbody>
</table>
## Appendix O

### Nurses’ Beliefs About Aromatherapy Scale Individual Item Mean Scores

<table>
<thead>
<tr>
<th>Item</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Based on sound scientific principles</td>
<td>4.35</td>
<td>1.556</td>
<td>281</td>
</tr>
<tr>
<td>Should be seen as part of conventional medicine</td>
<td>4.34</td>
<td>1.634</td>
<td>281</td>
</tr>
<tr>
<td>Involves changing the body as well as the mind</td>
<td>4.64</td>
<td>1.676</td>
<td>281</td>
</tr>
<tr>
<td>Essential oils can change brain chemistry</td>
<td>4.63</td>
<td>1.627</td>
<td>281</td>
</tr>
<tr>
<td>Can be used to treat depression</td>
<td>4.94</td>
<td>1.655</td>
<td>281</td>
</tr>
<tr>
<td>Can be used to treat anxiety</td>
<td>5.06</td>
<td>1.561</td>
<td>281</td>
</tr>
<tr>
<td>Can be used to treat phobias</td>
<td>4.61</td>
<td>1.633</td>
<td>281</td>
</tr>
<tr>
<td>Can be used to treat headaches, backaches, &amp; diseases</td>
<td>4.78</td>
<td>1.671</td>
<td>281</td>
</tr>
<tr>
<td>Most psychological &amp; medical research supports claims</td>
<td>4.08</td>
<td>1.544</td>
<td>281</td>
</tr>
<tr>
<td>Does not take long to work</td>
<td>4.90</td>
<td>1.464</td>
<td>281</td>
</tr>
<tr>
<td>Would benefit patients in my area of practice</td>
<td>5.01</td>
<td>1.697</td>
<td>281</td>
</tr>
<tr>
<td>I would recommend aromatherapy</td>
<td>4.86</td>
<td>1.823</td>
<td>281</td>
</tr>
<tr>
<td>Can be used to treat postoperative nausea &amp; vomiting</td>
<td>4.56</td>
<td>1.651</td>
<td>281</td>
</tr>
<tr>
<td>Can be used by nurses in labour &amp; delivery</td>
<td>4.93</td>
<td>1.531</td>
<td>281</td>
</tr>
</tbody>
</table>