Massage to prevent pressure ulcers: Knowledge, beliefs, practice and effectiveness

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Knowledge, beliefs, practice and effectiveness.

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Massage to prevent pressure ulcers:

Knowledge, beliefs, practice and effectiveness.

PROEFSCHRIFT

Ter verkrijging van de graad van doctor aan
de Universiteit Maastricht,
op gezag van de Rector Magnificus,
Prof. Mr. G.P.M.F. Mols,
volgens het besluit van het College van Decanen,
in het openbaar te verdedigen
op donderdag 15 december 2005 om 12.00 uur

door

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Promotores:

Prof. dr. M.P.F. Berger

Prof. dr. L.H.E.H. Snoeckx

Copromotor:

dr. R.J.G. Halfens

Beoordelingscommissie:

Prof. dr. R.A. de Bie (voorzitter)

Prof. dr. T.W.N. Dassen (Charité Universität, Berlin, Germany)

dr. ir. C.W.J. Oomens (Technische Universiteit Eindhoven)

Prof. dr. J.M.G.A. Schols

Prof. dr. R. De Wit

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Chapter 1

| Introduction |

Pressure ulcers, also commonly referred to as bedsores, pressure sores, decubitus ulcers or simply decubitus, can develop when sustained pressure, friction or shear is applied to specified areas of the body, in turn leading to degeneration of the skin and the underlying soft tissues.⁽¹⁾ As the name bedsores or decubitus ulcers (from Latin *decumbere*, to lie down) suggests, compression of the skin and deeper tissues between the hard, bony skeleton and the unyielding surface of a bed is the most common situation, but not the only condition initiating pressure ulcers.⁽²⁾ Sitting in a wheelchair or a regular seat, or wearing a prosthesis or orthosis can also cause pressure ulcers. In general, any situation in which a body area is subjected to continuous, unrelieved pressure can lead to the development of pressure ulcers.

In the Netherlands as in other countries, pressure ulcers are still a major problem in institutions for health care services.⁽³⁾ Estimations for 1998 revealed that more than 1% of the national health care budget was spent on prevention and treatment of pressure ulcers.⁽⁴⁾ These ulcers are a common and painful condition and cause a great deal of suffering and frustration, not only to patients themselves but also to their relatives and caregivers.⁽⁵⁾ Pressure ulcers can greatly extend the length of hospitalisation and can, in extreme conditions, even contribute to death.⁽²⁾

Until now, various treatments have been applied to prevent pressure ulcer development such as special mattresses, pressure-relieving cushions, repositioning schemes and nutritional support by a dietician. One of the methods which is also practised (whether or not in combination with other treatments) is massage. However, massage stopped being recommended as a preventive method as early as the 1980s.⁽⁶⁻⁹⁾ National and international guidelines regard massage as a method that could cause injuries to the skin.^(6, 8-10) Some authors even believe that massage actually provokes the development of pressure ulcers.^(11, 12) Nevertheless, research in Dutch health care institutions has found that almost all hospital nurses regarded the use of massage as a very effective preventive method.⁽¹³⁾ The same opinions were held by health care workers in Dutch nursing homes.^(14, 15) Although current guidelines advise against massage as a preventive method, it is essentially unknown whether massage is effective or not in preventing the development

of pressure ulcers. There are still some persistent, contradictory beliefs about the use and benefits of massage in guidelines, practice and the literature.⁽¹⁶⁾

Various theories have been forwarded to explain the aetiology of pressure ulcers, with most experts adhering to the theory that pressure ulcers result from chronic occlusion of capillary blood flow, leading to alternating periods of ischemia and reperfusion in the compressed tissue. Recently, it was shown in experimental animals that pressure ulcers can indeed develop as a consequence of ischemia-reperfusion injury, with toxic oxygen radicals apparently acting as important mediators in the pathogenesis of pressure ulcers.⁽¹⁷⁾ However, it should be noted these experiments were performed on healthy animals that had not previously suffered from vascular insults.⁽¹⁸⁾ Other studies with experimental animals found that the oral intake of antioxidants to inactivate the oxygen radicals had a preventive effect on the development of skin ulceration.⁽¹⁹⁾ Dimethyl sulfoxide (DMSO) is such a powerful, highly active scavenger of oxygen radicals, especially of the hydroxyl radical, and penetrates easily through the skin and other bio-membranes. In concentrations below 50% it is not toxic.^(20, 21)

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The research on which this thesis reports focussed on the effects of massage, whether or not in combination with DMSO, as a treatment to prevent the development of pressure ulcers in elderly patients.

Before discussing this aspect, this introduction outlines the physiology and blood supply of the healthy skin, and the available knowledge about the aetiology and pathogenesis of pressure ulcers. Finally it elaborates on the three main aspects of this thesis; the use of massage, the influence of DMSO and the specific features of nursing homes residents i.e. the elderly.

2 | Physiology of the skin

The skin constitutes the outer boundary between the human body and the environment, and functions both as a barrier and a connection between the outer world and the internal organs.⁽²²⁾ In an adult person, the skin accounts for 16% of the total body weight, and has a total surface of 1.2 - 2.3 m².^(23, 24) It is the largest organ in the body and has many crucial tasks, as summarized in Table 1.

Table 1 | Functions of the skin

- Maintenance of the body temperature through vasodilatation and constriction of the surface blood vessels.
- Protection from friction and shear, dehydration, ultraviolet light and radiation.
- Perception of temperature and pain.
- Perception of pressure, touch and vibration (collectively: tactile sensations).
- Excretion of small amounts of salts and perspiration (to aid thermal regulation).
- Synthesis of vitamin D.
- Prevention of loss of water and electrolytes.

10 | Structurally, the skin consists of three layers; the epidermis, the dermis and a subcutaneous layer (see Figure 1 on the inside of the cover). The epidermis contains stratified squamous epithelium, keratinocytes, melanocytes, Langerhans cells and Granstein cells, and can be divided into five layers.⁽²⁵⁾ The deepest layer is the *stratum basale* or *stratum germinativum* (1) which consists of basophilic columnar or cuboid epithelial cells, resting on the dermal-epidermal junction which separates the dermis from the epidermis. Together with the adjacent *stratum spinosum*, it constantly produces new cells. Aside from this, the *stratum spinosum* (2) provides resistance to mechanical disruption and contains nerve endings for sensation and touch. The *stratum granulosum* (3) contains keratocytes which provide colour to the epidermis and render it waterproof through the presence of keratohyatin. The *stratum lucidum* (4) is made up of several clear, flat dead cells, and is found only on the palms of the hands and the soles of the feet where the skin reaches its greatest thickness. Finally, the *stratum corneum* (5) consists of 25 - 30 layers of closely packed dead cells. These cells contain keratin and are constantly shed at a 27-day turnover rate. This layer is tough and waterproof and acts as a barrier to bacteria and chemicals.⁽²⁴⁻²⁷⁾

The underlying dermis or corium consists of two layers; the upper *stratum papillare* (1) and the deeper layer or *stratum reticulare* (2).⁽²⁶⁾

Essentially it is a thick layer of strong connective tissue containing blood vessels, nerves, glands and hair follicles. It is connected to the epidermis by connective tissue.⁽²⁵⁾

Going further inward, the dermis changes into the subcutis without a clearly defined boundary. The entire subcutis contains adipose tissue, the purpose of which is to isolate the body and to cushion.^(26, 27)

3 | Blood supply of the skin

The distribution of blood vessels in the skin parallels the layered structure of this organ. From the arteries lying under the subcutaneous tissue, numerous vessels arise which form a cutaneous plexus between the subcutaneous plexus and the dermis. Wherever the skin is more mobile, the vessels take a pronounced tortuous course. The individual arterioles run outwards perpendicularly to the deep cutaneous plexus. At the foot of the papillary layer they branch into the subpapillary plexus. Very fine loop-like capillaries extend from there into the papillae of the dermis and thus ensure perfusion of the epidermis. Figure 2⁽²²⁾ (on the inside of the cover) shows a schematic diagram of the blood supply to the skin.

The vascular circulation can be classified into three distinct systems: segmental, perforator, and cutaneous circulation.⁽¹⁸⁾ The segmental system comprises the body's main distributing vessels stemming from the aorta. Nutritional blood supply to the muscle is provided by the perforator system. The third, cutaneous system, consists of the supplying arteries, capillary beds, and drainage veins in the skin. In addition to providing the skin with metabolic substrates and removing its waste products, the cutaneous system also plays an important role in the thermoregulation of the body. In relation to its metabolic needs, the skin is actually oversupplied with blood.⁽⁴⁾

4 | Aetiology and pathogenesis of pressure ulcers

4.1 | The grading and prevalence of pressure ulcers

The European Pressure Ulcer Advisory Panel (EPUAP) defines a pressure ulcer as an area of local damage to the skin and underlying tissue caused by

pressure, shear and/or friction or a combination of all these factors.⁽²⁸⁾ Clinically, pressure ulcers most often appear in the tissues covering bony prominences. Studies in animals have shown that muscle and subcutaneous tissue are more susceptible to pressure-induced injury than the epidermis.⁽²⁹⁾ The EPUAP has classified pressure ulcers into grades I-IV (see Figure 3 on the inside of the cover).⁽³⁰⁾ This grading system is based on a clinical description of the severity of the localised damage which is due to pressure, shear or friction, and says nothing about the cause, the duration, the aetiology or the pathogenesis. Agreement on the grading of the severity of pressure ulcers is important for treatment and research, and for scoring prevalence and incidence rates. Therefore management should be based on a uniform classification.

In 2004, the general prevalence rate of pressure ulcers in Dutch health care institutions ranged from 14.2% to 30.5%. Nursing homes had the poorest results with a prevalence rate of 30.5%.⁽³¹⁾ In this environment pressure ulcers developed most frequently at the coccyx (27.8%) and the heels (33.8%).⁽³¹⁾

4.2 | Aetiology of pressure ulcers

In addition to pressure, shear and friction, other risk factors can also affect patients' susceptibility to pressure ulcers.^(16, 32) Such factors are sensory perception, level of activity and mobility and factors affecting tissue tolerance such as moisture, nutrition, and friction and shear. These factors are also included as subscales in the Braden scale, a tool for evaluating the pressure ulcer risk.⁽³⁷⁾ At present, it is generally accepted that mechanisms underlying the aetiology of pressure ulcers are rather complex and still not fully understood.⁽³³⁾ What nurses and other care professionals know about the factors causing pressure ulcers is very often restricted to the extrinsic and external influences. The main *extrinsic factors* leading to tissue damage are pressure, friction and shear forces and the duration of these forces.^(25, 33-36) However, it is well established that pressure ulcers can also be provoked by such *intrinsic factors* as the level of blood supply and lymphatic drainage, reperfusion injury and cellular deformation.⁽¹⁶⁾ Other, more individually deter-

mined intrinsic factors also increase the vulnerability to pressure ulcer development, such as general health, reduced mobility, reduced activity, body weight, incontinence and nutrition level.^(1, 25, 32, 37-42) Finally, *external factors* such as long trolley waits in emergency departments, hard chairs, immobilization with traction, poor positioning and poor lifting techniques can affect the development of pressure ulcers.^(25, 33)

4.3 | Pathophysiology of pressure ulcers

Several theories have been proposed to explain how compressive tissue straining leads to local cell damage.⁽⁴³⁾ The three main hypotheses on how mechanical load leads to tissue damage are the following:

1. *Poor blood supply and lymphatic drainage:*

It is well known that pressure and immobility leads to the continuous compression of venous blood vessels and, consequently, to reduced blood flow in the compressed tissue. As a result, cells receive less oxygen and are unable to remove their waste products, ultimately leading to irreversible cell damage. In addition, the lymphatic system is compromised by immobility and by excessive mechanical stress, so that the tissues are not adequately drained.^(18, 44, 45)

2. *Reperfusion injury:*

A more recent hypothesis, mainly based on results obtained with experimental animal models, is that post-ischemic reperfusion leads to tissue damage through the enhanced local production of oxygen free radicals.^(17, 46) These radicals arise in the cells and are responsible for cell damage since they degrade membrane lipids. Tissue injury also increases with an increasing number of total ischemia-reperfusion cycles, the duration of the ischemia and the frequency of ischemia-reperfusion cycles.^(46, 47)

3. *Cell deformation:*

Another recent hypothesis concentrates upon cellular deformation. Continuous excessive deformation of the cell triggers a variety of effects which may be involved in early cell damage, such as local membrane stresses

which may lead to buckling and bursting of the membrane, volume changes and modifications of the cytoskeletal organisation affecting the cell's integrity.⁽⁴⁸⁾ Hence, the cause of cell damage could be a direct consequence of sustained cell deformation or of impaired transport of both metabolites and waste products within the cell and in the surrounding tissue.⁽⁴⁹⁾ Nevertheless, the relationship between local cell damage and the load magnitude and time is still unclear.⁽⁴⁹⁾

4.4 | Development of pressure ulcers

Two theories have been postulated to explain the site-specific development of pressure ulcers. According to the traditional so-called top-down theory, pressure ulcers are initiated in the epidermis, and later expand into deeper lying tissues. In contrast, the bottom-up approach presumes that the pressure ulcer starts in the deeper tissue layers, in close proximity to the bone. This would imply that microcirculatory changes in the deeper tissue layers are more deleterious than what can be perceived on the skin surface.^(50, 51)

The top-down theory states that the most striking effect of pressure ulcers, starting from grade I, is the irreversible redness, also called the non-blanchable erythema. As continuous compression occludes tissue blood flow, interferes with lymphatic circulation and deprives the tissues of oxygen, nutrients and waste removal⁽⁵²⁾, cells produce toxic metabolites, leading to tissue acidosis, increased capillary permeability, oedema and finally cell death resulting in a non-infectious inflammation reaction.^(1, 52) Finally, the skin turns red and feels warmer. This theory is supported by experimental findings that relate skin blood flow to the level of externally applied pressure. When the latter exceeds the normal capillary blood pressure (32 mmHg or 4.27 kPa), fluid leakage from the vessels into the extracellular space will initiate oedema.⁽⁵³⁾ This oedema further hampers proper circulation, so that tissue pressure will continue to increase. Eventually, haemorrhage develops, which is responsible for the non-blanchable redness of the skin.⁽⁵¹⁾ If pressure is relieved in time and perfusion of the tissues can be restored, such that toxic metabolic waste products are adequately removed, the redness may disappear. This situation is known as blanchable erythema.⁽⁵²⁾

The *bottom-up approach* assumes that the skin is less sensitive to pressure-induced damage than the underlying deeper tissues.⁽⁵³⁻⁵⁵⁾ When blood flow in the deep layers is interrupted, muscle tissue can be damaged.⁽⁵⁾ The combination of prolonged pressure and blood flow deficit can cause ischemia of the skin tissue and non-blanchable redness of the skin will appear. The interruption of the blood flow in the deeper layers irreversibly damages muscle tissue and the circulation to superficial layers becomes permanently deteriorated.⁽⁵¹⁾ If damage to the deeper underlying tissues is far advanced, sclerosis of the necrotic tissue can also be detected through palpation.⁽⁵⁶⁾ Such deep ulcers arising in the deep muscle layers covering bony prominences are very harmful, develop at a faster rate than superficial ulcers and yield more extensive ulceration.⁽⁵³⁾

5 | The use of massage

The natural human response to pain in the skin or underlying tissue is to use touch to alleviate it. Based upon this knowledge, the art of massage has been developed long ago. Indeed, it is described in writings dating from before 2000 B.C..^{(1), (57)} However, some physiological and therapeutic effects of massage are still being questioned, especially regarding its use as a preventive treatment for the development of pressure ulcers.⁽⁵⁸⁾ The purpose of the present thesis was to gain a better insight into the role of massage in the pressure ulcer problem, especially among the elderly. The project started with a literature study, which intended to summarize the state of the art regarding the effects of different massage techniques. Furthermore, it identified the most important general indications and contra-indications for massage, and summarized these for application in patients prone to developing pressure ulcers.

6 | Influence of radical scavengers

In tissue affected by pressure ulcers, like any tissue in which inflammation occurs, repetitive ischemia-reperfusion episodes can lead to the local forma-

tion of reactive oxygen species. Briefly, leukocytes are recruited during the reperfusion process after an ischemic event, for instance secondary to excessive tissue pressures. Adhesion molecules are expressed by the endothelial surface, and the leukocytes roll, stick and migrate into the tissue. There they express pro-inflammatory cytokines and release destructive free radicals.⁽⁵⁹⁾ At the cellular level, the release of oxidants is a stress event and aged cells are less equipped to deal with these events than non-aged cells.⁽²⁹⁾ The main representatives of these radicals are the super oxide anion (O_2^-), hydrogen peroxide (H_2O_2) and the hydroxyl radical ($OH^\cdot$). Since dimethyl sulfoxide (DMSO; $(CH_3)_2 S-O$) is known to be a hydroxyl-inactivating compound, it can be assumed that its beneficial effects on pressure ulcers are based upon the inactivation of the hydroxyl radical.

Besides to be a water-white to straw-yellow organic liquid, DMSO is a colorless, oily substance with a smell of sulphur and a slightly bitter taste. In topical application this simple, highly polar chemical compound has been found to alleviate local ischemic damage in several experimental animal models.^(60, 61) In addition to its analgesic effect, the most important property of DMSO is the enhancement of percutaneous penetration, so that it is often used as a carrier for active drug-containing creams.⁽²¹⁾

The use of DMSO in preventing pressure ulcers is rather recent in spite of the fact that the compound is a well-known agent in physiotherapy and dermatology. Indeed, DMSO is known for its anti-inflammatory, wound-healing and pain-relieving effects.⁽²⁰⁾ Based on the knowledge that DMSO has an anti-inflammatory operating mechanism, a pilot study⁽⁶²⁾ was set up in elderly patients to investigate any beneficial effect of DMSO to prevent the development of pressure ulcers. This pilot study revealed that rubbing the intact skin with a DMSO-containing cream during the first stage of pressure ulcers (according to EPUAP's four grade system) led to a decrease in pressure ulcer occurrence among high risk patients. Based on this pilot study and a literature study⁽²⁰⁾ about the effects of DMSO, we initiated a subclinical trial to evaluate the effects of a DMSO-containing cream on the development of pressure ulcers in patients prone to them.

For the studies described in the present thesis, only patients of Dutch nursing homes were invited to participate because in the Netherlands they have the highest prevalence rates of pressure ulcers and the population is rather stable over a long period.⁽⁶³⁾ The high prevalence rates in this population can partly be explained by the age-related changes to the skin, such as the loss of dermal vessels, thinning of the epidermis, flattening of the dermal-epidermal junction, loss of elastic fibres and increased skin permeability, and increased susceptibility to skin breakdown.⁽²⁹⁾ It also seems that wound-healing impairment is additive, if not synergistic, when age and ischemia are combined.⁽⁵⁹⁾ Aged cells show a decreased proliferative capacity with prolonged doubling times and eventual replicative senescence. These changes most likely affect the altered stress response in the aged and play a role in chronic wounds.⁽⁵⁹⁾

In this dissertation, the beliefs and knowledge about massage among Dutch nurses and health care givers, their use of this treatment and its effectiveness in preventing pressure ulcers have been investigated. The aim of this thesis is to clarify the existing discrepancy between theory and practice regarding the use of massage as a preventive method for pressure ulcers in the Netherlands. Therefore, this thesis consists of two parts. In the first part, we describe results obtained from literature studies on the effects of different massage-techniques and on the efficacy of topical skin application of DMSO. The second part presents and discusses the results of our empirical studies. The beliefs and the knowledge about and the use of massage were investigated in the light of the current guidelines. Furthermore, it was also investigated if relations exist between these three aspects and the pressure ulcer policy of individual institutions on the one hand, and institutional prevalence rates on the other hand. Finally, the effectiveness of massage - whether or not in combination with DMSO - was investigated by means of an R.C.T. in patients of Dutch nursing homes.

PART 1 | Literature studies

Chapter 2

Well-controlled studies of the preventive effects of massage on the development of pressure ulcers in a geriatric population are scarce. Therefore, we performed a literature study, in order to survey the existing knowledge about the general effects of skin massage. The chapter reports on indications and/or contra-indications for the application of massage in patients prone to pressure ulcers, both in general and more specific terms.

Chapter 3

In a systematic review we investigated the present state of knowledge regarding the use of DMSO in the prevention of pressure ulcer development. This chapter reports the results of our evaluation with respect to wound healing and anti-inflammatory effects of different concentrations of DMSO, administered by topical application to the skin.

PART 2 | Empirical results

Chapter 4

To assess nurses' current knowledge and beliefs about massage to prevent pressure ulcers, and their use of this treatment, a study was designed to evaluate the changes in these three aspects after the publication of the 2002 Dutch national guidelines.⁽⁶⁴⁾ We compared the outcome of this study with the situation in 1991, the year in which the previous guidelines and nurses' knowledge, beliefs and practice were investigated. This enabled us to determine whether any changes had occurred between 1991 and 2003.

Chapter 5

This chapter reports on a study that further elaborated on the results described in chapter 4. The aim of this study was to find out whether or not the pressure ulcer policy of individual institutions was related to the nurses' knowledge and their use of massage, and to the prevalence rate of pressure ulcers in each institution. To this end, data were analysed at an aggregated

level by incorporating results and investigated characteristics as described in the National Prevalence Study of Pressure Ulcers 2003, the results of which were obtained from inquiries in the same institutions and wards, as described in chapter 4. Eventually, the evaluation of the results drawn on individual level (micro-level) was related to the results found in the annual Dutch national prevalence survey of 2003 at institutional level (macro-level). At the micro-level, we analysed the nurses' knowledge about massage and their use of it in practice, whereas at the macro-level we included the institutions' prevalence rates and PU policy features.

Chapter 6

The purpose of the study described in this chapter was twofold. In a well-controlled randomized clinical trial on patients prone to pressure ulcers, we evaluated the effects of massage in the prevention of pressure ulcers by comparing massage treatment with a treatment that only consisted of a regular body position changes. Secondly, we evaluated the effects of massage in combination with a DMSO-containing cream on the incidence of pressure ulcers. This chapter reports the main findings of this clinical trial and discusses the effects of massage, with and without DMSO, as a method to prevent pressure ulcer development.

Chapter 7

Chapter 7 presents the final conclusions of this thesis and elaborates on several theoretical and methodological issues. Furthermore, it presents recommendations for further investigations and for the daily practice of preventing pressure ulcers.

The chapters in this thesis, with the exception of chapters 1 and 7, are all based on articles published in or submitted to scientific journals. Since this implies that they were all intended to be read independently, some overlap between the chapters is inevitable.

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Chapter 2

The effects of massage as a method to prevent pressure ulcers. A review of the literature.

Inge GP Duimel-Peeters, Ruud JG Halfens, Martijn PF Berger,
Luc HEH Snoeckx

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General information about the effects of massage to prevent pressure ulcers is limited. A literature search was conducted to provide more detailed knowledge about the effects of massage in general and in preventing the development of pressure ulcers in particular. Using the keywords massage, rubbing, prevention of pressure ulcers/pressure sores, and paying particular attention to referenced articles yielded a summary of different manual massage techniques and indications/contraindications of this intervention for both healthy tissues and tissues in patients at risk for developing pressure ulcers. A careful review of this information; the clinical, physical, and pathophysiological aspects of pressure ulcers, including extrinsic and intrinsic factors; and the time-pressure relationship suggests that one type of massage may be beneficial for persons who are at risk for developing pressure ulcers, although based on currently existing studies, it cannot be proven statistically that massage is an adequate preventive method for pressure ulcers. Although many guidelines advise against the use of massage in people at risk for pressure ulcers, current evidence suggests that research to increase knowledge about the mechanism behind the effects of massage as a part of an individual prevention and treatment plan should be conducted.

Touch is a natural human response to alleviate pain in the skin or underlying tissue. Physical contact, particularly involving hands, can be an essential component of the healing process.⁽¹⁾ The art of massage was developed long ago based on this knowledge; references to massage can be found in writings earlier than 2000 BC.^(2,3)

Although a considerable amount of information is available on the mechanical, physiological, and relaxing effects of massage, as well as on its indications and contraindications, little is known about its ability to prevent the development of pressure ulcers (PU). Some physiological and therapeutic effects of massage are still questioned⁽⁴⁾; moreover, the potential for massage to prevent PUs is widely criticized. Some authors believe it actually causes the development of pressure ulcers.⁽³⁾

A literature review was conducted to address existing contradictory opinions about the effects of massage and to provide enhanced insight into the role of massage in the PU development, especially among elderly. This article summarizes the state of the art regarding the effects of different massage techniques, identifies the most important general indications and contraindications for massage, and offers applications for practice in patients prone to developing pressure ulcers. The reviewed literature was obtained through a search of Medline and Pubmed using the keywords *pressure ulcer (PU)*, *massage*, *rubbing*, *prevention of PU*, and by examining the references of all retrieved articles. Conclusions about the effectiveness of massage in preventing PUs are presented following a short description of the aetiology and the pathophysiology of PUs and existing information about the mechanical and physiological effects of massage.

2 | Different massage techniques

Manual massage techniques are divided in two general categories - Swedish and Chinese (the latter is discussed elsewhere).⁽²⁾ Swedish massage is applied on muscle, tendons and soft tissue. French terminology is used to differentiate between stroke types.^(2,5)

Effleurage (a stroke that glides). Effleurage consists of slow, rhythmic stroking hand movements moulded to the shape of the skin and is frequently used to start and finish a treatment session. The strokes pass from distal to proximal and parallel the long axis of the tissue. Firm pressure is believed to accelerate blood and lymph flow, to improve tissue drainage and, as such; to reduce swelling.⁽⁵⁻⁹⁾

Petrissage (a stroke that kneads). Petrissage or skin rolling is a forceful technique that can only be applied to fleshy regions of the body. A fold of skin, subcutaneous tissue, or muscle is squeezed, lifted, and rolled in a continuous circular motion against the underlying tissues.⁽⁵⁻⁷⁾ This method is particularly useful for stretching contracted or adherent fibrous tissue and to relieve muscle spasm.

Tapotement (striking). Tapotement is the general name given to percussive massage techniques. Vigorous tapping vibrates tissues and triggers cutaneous reflexes such as vasodilatation.⁽⁵⁻⁸⁾ Vasodilatation, in turn, increases muscle tone and promotes interstitial fluid circulation, reduces swelling, and accelerates healing processes.^(6,7,10)

Friction (compression). Friction is an accurately delivered penetrating pressure applied in small areas with the fingertips. It is especially effective for the treatment of adherent or contracted connective tissue^(5,6); therefore, it is specifically recommended in sports therapy.

Vibrations (shaking or vibrating). Vibrations are delivered by trembling both hands held firmly in contact with the skin. Unlike effleurage, this method compresses swollen tissue and can reduce edema with less risk of spreading infection.⁽⁵⁾ This technique is mostly used in respiratory physiotherapy.

3 | When is massage generally indicated or contra-indicated?

Nurses and other health care givers using manual massage need to know whether massage is appropriate. In healthy tissues, massage is known to have the following advantageous effects: encouraging hyperaemia as a consequence of histamine release, increasing tissue suppleness, relaxing muscle tone, increasing parasympathetic activity, reducing edema, relieving subcutaneous scar tissue, and activating mast cells.^(2,7-9,11,12) However, massage is con-

tra-indicated when tissues are inflamed or when the risk for malignant cells to spread along the skin or through the lymph or the blood stream (lymphangitis, malignant melanoma) is increased. Massage is also contra-indicated when patients are prone to bleeding (ecchymosis), have disorders of the circulatory system (phlebitis, severe atherosclerosis), and have abnormal sensations due to stroke, diabetes, and medication.^(2,13) Long-term massage is also known to cause desquamation (the skin peels or comes off in scales) - described by the European Pressure Ulcer Advisory Panel (EPUAP) guidelines as grade 2 of pressure ulcers.⁽¹⁴⁾

Opinion is divided on the use of massage in patients prone to pressure ulcers. Some authors are convinced that massage prevents the bedridden patient from developing pressure ulcers, particularly if the patient is unable to move.^(1,2) However, when such patients show signs of acute tissue inflammation, massage treatment can be counterproductive. As such, recognizing early signs of inflammation is important and increasing numbers of clinicians agree that pressure ulcers are related to a form of chronic inflammation.⁽¹⁵⁻¹⁷⁾

30 | The literature indicates that effleurage was the preferred technique in the treatment of pressure ulcers and should be applied with moderate pressure because unnecessarily high pressures are harmful to underlying tissues.⁽¹⁸⁻²⁰⁾

Other massage techniques such as tapotement and friction are rather painful, making them disadvantageous for use in the thin, elderly patients. Also, because friction can easily cause mild tissue destruction or provoke an inflammatory reaction, it is contra-indicated for people who are not in good health.^(5,6)

4 | Clinical and physical aspects of pressure ulcers

With the average age of the population on the increase and improved medical care prolonging life, the medical profession is faced with the increasing problem of caring for the elderly and people with disabilities. Pressure ulcers are a common problem in this population, developing locally where soft tissue is compressed between a bony prominence and a firm surface for a prolonged period.^(16,17) Pressure ulcers occur in superficial as well as deeper layers of the skin or even in the underlying muscles. The EPUAP classification system is

the most commonly used international grading system to determine the grade of a PU (Table 1).⁽¹⁴⁾

Table 1 | Grading System of Pressure Ulcers

Grade	Description
I	Non-blanchable discoloration of intact skin;
II	Partial-thickness skin loss involving epidermis, and/or blister or shallow ulcer without undermining of adjacent tissue;
III	Full-thickness skin loss involving damage or necrosis of the epidermis and/or dermis not extending to underlying bone, tendon or joint;
IV	Full-thickness skin loss involving damage or necrosis of the epidermis and/or dermis extending to underlying bone, tendon or joint.

4.1 | Physiology of the skin

The skin constitutes the outer boundary of the human body and functions both as a barrier and as a connection between the outer world and the internal organs.⁽¹⁵⁾ The skin accounts for 16% of the body's total weight and has a total surface area of 1.2 to 2.3 m² in an adult person.⁽²¹⁻²³⁾ The largest organ in the body, the skin fulfils many essential tasks (see Table 2). Clearly, these functions can be threatened when the skin is damaged by a PU.

Table 2 | The Functions of the Skin

-	Maintenance of body temperature through vasodilatation and constriction of the surface blood vessels
-	Protection from friction and shear, dehydration, ultraviolet light and radiation
-	Perception of temperature and pain
-	Perception of pressure, touch and vibration (collectively: tactile sensations)
-	Excretion of small amounts of salts and perspiration (aids thermal regulation)
-	Vitamin D synthesis
-	Preventing loss of water and electrolytes

4.2 | Extrinsic factors involved in the development of pressure ulcers

The risk of PUs can be provoked by extrinsic and intrinsic factors. The three extrinsic factors related to PU development are pressure on and shear and friction within the tissue.⁽²⁴⁻²⁷⁾ Intrinsic factors include poor blood supply that causes ischemia, reperfusion injury, and inflammation in the affected tissue.

Pressure is created when soft body tissue is compressed between a hard surface and a bony prominence. If this pressure is higher than the capillary pressure, local blood flow is reduced and ischemia may result.^(16,28) The location of the onset of pressure ulcers is influenced by the nature of the external loading. Pressures applied perpendicularly on the skin above a bony prominence, simultaneously compress a small part of subcutaneous fat and muscle tissue above that prominence, potentially causing extensive damage that commences from locations deep within the muscle tissue layer without visible signs at the skin surface.⁽²⁹⁾ This effect will be strengthened because the skin is mechanically stronger than underlying tissues and is better equipped to survive periods of ischemia.⁽³⁰⁾ In contrast, superficial pressure ulcers are mainly caused by shearing forces and initiate in the skin with maceration and detachment of the superficial skin layers.⁽³¹⁾ In addition, deep ulcers develop at a faster rate than superficial ulcers, making them even more harmful.⁽³¹⁾

Local tissue shear forces are typically problematic when a patient is sitting (chair or wheelchair) for several hours.⁽²⁷⁾ Shearing forces destroy the microcirculation by causing thrombosis of the vessels.⁽³²⁾ Preventing the patient from sitting in a tangential way - the position in which most often shear forces occur - is important.⁽³³⁾

Friction is a periodic change in shear and occurs when one surface is moving rhythmically over another, such as when the patient is semidependent and semirecumbent, and is inadequately/infrequently lifted from a bed. Friction can cause stripping of the skin, leading to superficial ulceration.⁽²⁷⁾

A preventive strategy developed to address extrinsic factors provoking pressure ulcers should be based on avoidance or reduction of shearing and friction forces and/or relief of excessive local pressure at all body-support interfaces.⁽³⁴⁾ However, individual susceptibility to pressure ulcers can vary

substantially and affect any measure taken to reduce pressure, shear, or friction.⁽³⁵⁾

4.3 | Intrinsic factors involved in the development of pressure ulcers

A. Blood supply to skin and muscle

Interruption of the normal blood supply to skin and muscle by increased localized pressure can result in tissue ischemia and hypoxia when the resultant pressure is greater than capillary pressure and persists over a critical time period.⁽²⁷⁾ Eventually, this can lead to tissue necrosis. Furthermore, when pressure on an ischemic area is relieved, a red area appears on the skin over the bony prominence due to a reactive hyperaemia. This phenomenon is typical for tissue that is still viable and characterizes the normal response after temporal flow reduction. In contrast, when the red area does not blanch when light finger pressure is applied, this is termed non-reactive hyperaemia. This event is a typical precursor to the development of pressure ulcers.⁽²⁷⁾ The same type of tissue breakdown or necrosis results from pressure-induced muscle ischemia in bedridden patients. Continuous compression interrupts blood and lymph flow and deprives the tissue of access to oxygen and nutrients, and toxic waste product removal. Individual cells produce toxic metabolites that cause tissue acidosis, increased capillary permeability, edema, and eventually necrotic cell death.^(17,27) Pressure ulcerations are localized areas of cellular necrosis. Where normal cell metabolism is dependent on the receipt of nutrients and the elimination of metabolites, compression will interfere with this exchange.⁽¹⁶⁾ Because muscle tissue has a lower tolerance to local ischemia than the skin, tissue necrosis conceivably could occur earlier in compressed muscle than in the skin.⁽¹⁷⁾

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B. Reperfusion injury

In compressed tissue, blood flow can be restored intermittently, suddenly reperfusion the tissues with oxygenated blood. Paradoxically, this phenomenon can also be harmful, causing occlusion-reperfusion injury.⁽³⁶⁾ Due to the sudden increase in oxygenation and the ischemia-induced suppression of enzyme activity, oxygen-related free radicals can damage cell membranes and initiate the process of cell necrosis.

C. Inflammation

Prolonged ischemia and reperfusion injury both cause serious tissue damage, leading to cell necrosis⁽²⁶⁾ that, in turn, will initiate an inflammatory response characterized by vasodilatation leading to redness of skin and increased temperature. Furthermore, the tissue swells due to increased permeability of blood vessels. This process is associated with pain, probably caused by tissue distortion and production of chemical mediators. Eventually the various events can cause thrombosis in the capillaries.

4.4 | Time-pressure relationship and the interstitial fluid compartments

Extensive research in experimental animals and humans has shown that the development of pressure ulcers depends on the pressure level and the duration of the pressure on the tissue (see Figure 1), and the direction of pressure.⁽²⁰⁾

Figure 1 | Pressure ulcer risk curve. Pressure/time combination above the curve will lead to tissue breakdown.^(28,29)

Increasing the surface of the body in contact with the bottom tissue layer can reduce the intensity of pressure.⁽³³⁾ Varying the amount of pressure and

the length of time seems to create an inverse relationship between tissue damage and external load magnitude and duration.^(28,29) Thus, a large- load magnitude applied during a short time and smaller loads applied for prolonged times result in tissue damage.^(16,28-30) An explanation for this time-pressure relationship is not immediately at hand. Stagnation of blood flow cannot be the only reason for damage; otherwise, every pressure high enough to cut off a vein would lead to pressure ulcer development. A possible explanation could be that pressure and shear lead to a local pressure increase in the interstitial fluid between the cells. Consequently, the fluid will stream slowly away to areas with lower pressure. In these areas, cells will experience a higher pressure, resulting in breakdown through mechanical overloading.^(28,30)

5 | Discussion: the use of massage to prevent pressure ulcers

Massage on healthy tissues supports adequate tissue blood perfusion; encourages lymphatic drainage, thereby reducing edema; provides gentle stretching of tissue; and relieves subcutaneous scar tissue.^(2-4,6,37-41) This suggests that massage, and especially effleurages, is effective in the prevention of pressure ulcers because tissue drainage is improved, swelling is reduced and vascularization is normalized. However, when massage is applied on tissues prone to the development of pressure ulcers, it can have a deleterious effect, provoking further cell damage through the excessive formation of oxygen free radicals as a consequence of hyperaemia.⁽³⁶⁾ Nevertheless, this negative effect can be balanced through the restoration of necessary blood flow. Cellular metabolic homeostasis is better preserved and toxic metabolites are better removed through improved blood circulation (see figure 2). Studies conducted on the effects of massage on skin, immunity, blood flow, and pressure ulcers are summarized in Table 3.

5.1 | Arguments in favor of massage as a preventive method in the PU development

In a review of mechanical methods of preventing pressure ulcers in elderly patients, Bliss⁽³²⁾ claims that purposeful effleurages over threatened areas once or twice daily were effective in preventing the development of pressure ulcers. The additional consequence of rubbing the patient twice daily is a change of position and pressure relief on the compressed areas twice a day. The change of position can cause effect-modification. However, the author of this study did not mention how a possible source of bias was addressed. Célice⁽⁴²⁾ describes positive effects of robust massage for 15 minutes to prevent pressure ulcers in bedridden patients. At the end of each massage session, a slight bloodstained pink color appeared at the treated body part, indicative of hyperaemia. Besides this visual observation, the results of this study lack statistically scientific evidence. A pilot-study performed by van den Bunt⁽⁴³⁾ shows a positive effect of massage on the prevention of pressure ulcers. The author claims that rubbing the patient prevents the development of PUs but did not mention how. This finding is not supported by any scientific argument; furthermore, the type of massage used is not clear. Although the study found that massage has positive effects, it does not provide more scientific information - specific definitions of "rubbing", "regularly", "massage" and "positive effects" were absent.

Iwama⁽⁸⁾ and Ironson⁽⁹⁾ investigated the effect of massage on the immune system by collecting blood before, during, and after completion of massage. They found that massage had a stimulatory effect on the sympathetic nerves (relaxation) and activated and increased the number of natural killer cells. They concluded that massage prevents the occurrence of PUs through the reactivation of the depressed immune system, as observed in elderly bedridden patients. They are convinced that skin rubdown (i.e., robust massage) should be recognised as a simple health procedure that improves cellular immunity. Corley⁽³⁹⁾ notes that several physiological measures, such as heart rate and blood pressure, did not change significantly after back rub massage; however, the group of patients studied showed a significant

increase in skin temperature. More than half of the persons treated said they felt more relaxed and relieved of pain after the massage. In addition, patients experienced a significantly positive change in mood in comparison with the control group, which for instance, resulted in a better night's rest.

5.2 | Arguments against massage as a preventive method in the PU development

Opponents of massage as a method to prevent the development of pressure ulcers claim it has no effect or inflicts more harm than benefits. The outcome of Ek's study⁽⁴²⁾ show that massage on normal skin had an inconsistent and non-significant effect on blood flow as measured by laser Doppler flowmetry. Furthermore, patients with skin discoloration reacted with a reduced blood flow after the massage was implemented. Frantz⁽⁴⁰⁾ found the same inconsistencies when looking at the single effects of prolonged pressure on skin blood flow over the trochanters of 16 elderly patients at risk for pressure ulcers. Blood flow tracings in the skin during a 60-minute period of continuous pressure revealed an inconsistent pattern of response; the flow increased, decreased or showed no change. Although this study involved a relatively small number of patients undergoing pressure for a single 1-hour session, results implied that additional studies with larger populations over longer periods of time are warranted. Braden⁽¹⁹⁾ states that massage to prevent pressure ulcers is no longer considered appropriate skin care and is even harmful if ischemic injury is already present. Massaging a non-blanchable skin discoloration to prevent further damage is pointless because the blood vessels already are dilated; thus, massage may force toxic substances to leak into the interstitial space, which, in turn, may cause tissue damage. Olson⁽²⁰⁾ also does not recommend extensive massage to a formerly compressed area because circulation would be further compromised; however, the small sample size, lack of a control group (i.e., group without massage), and the participation of a unique population (patients with fractured hips) limits the generalization of the results. Meaume⁽⁴⁴⁾ states no confirmed reports of efficacy support the widespread usage of massage in France and further argues that rubbing pressure ulcers, especially grade I ulcers, should be contra-indicated

because underlying tissues are damaged by decreased blood flow and, consequently, elevated skin temperature. Dyson⁽¹⁸⁾ studied the effects of massage on geriatric patients over a 6-month period and found the incidence of pressure ulcers was greatly reduced if patients were not rubbed at all; on post-mortem examination, massaged areas exhibited macerated and degenerated tissue, while unmassaged tissue remained healthy with no signs of tearing. The author did not stipulate the massage technique used - only the term vigorous is mentioned. However, in the past massage meant strong rub and pinch - this is not the way effleurages are performed today. Dyson's findings are interesting but lack scientific documentation on the methods and conditions of the research.

The questionable usefulness of petrissage, tapotement, friction and vibration in the treatment of elderly patients prone to pressure ulcers has met with considerable agreement.^(5-7,10,11,20,38,44)

Petrissage (skin rolling) is a forceful technique. Because of its effects and means of application, it is completely contra-indicated in the prevention and treatment of pressure ulcers. Petrissage is harmful to underlying tissues, especially when they are in a compromised condition. Meaume⁽⁴⁴⁾ reports that this technique has been abandoned in France and replaced by effleurage. Hovind and Nielsen⁽³⁸⁾ conclude that petrissage has a variable and inconsistent effect on blood flow but that hyperaemia is absent.

Physiologically, tapotement provides an immediate increase in blood flow during the treatment, reaching values 35% higher than normal.⁽³⁸⁾ However, because it is rather painful, the technique is deleterious, especially in thin, elderly patients. The same may be said for friction, which can be painful and stimulates a marked local hyperaemia or an inflammatory reaction.^(2,5) Vibrations are also not recommended in the prevention of PUs because of the extended and robust way of performing this type of massage. Several authors have suggested that vigorous massage over bony prominences should be avoided because it provokes muscle damage not visually apparent.^(18,20)

Figure 2 | Pathophysiology of pressure ulcers and influence of massage.⁽¹⁵⁾

6 | Conclusion

According to data presented in the literature, massage has some advantageous effects on the skin. It increases blood flow, stimulates skin suppleness, and relaxes the tissue. In addition, massage reduces certain types of edema. An important disadvantage is the potential to cause damage to underlying tissues, a consequence of using the wrong type of massage or of not taking into consideration that pressure ulcer - related damage is already present.

This review shows that the effect of massage on the prevention of pressure ulcers varies between different studies and authors with regard to local skin blood flow and temperature, individual differences, and normal versus

injured skin. Although healthcare workers often believe in the preventive effect of massage⁽⁴⁵⁾, no clear scientific evidence has yet been presented in terms of the beneficial effects of massage in the prevention of pressure ulcers, particularly among the elderly and people at risk.

However, because of the relatively small number of participants and questionable methodological quality of the studies, contra-indications may, in some cases, be worthy of the benefit of the doubt. Massage (i.e., effleurages) may be beneficial in some instances after careful consideration of the patient's physical condition and medical history and respecting individual variability in administering massages. The mechanism behind the effects of massage is still an important field for research.

Table 3 | Summary of Studies on the Effects of Massage on Skin, Immunity, Blood Flow and Pressure Ulcers.

Authors	Watts, Nunn* (2002)	Ironson, Field * (1996)	Corley* (1995)	Van den Bunt* (1996)	Ek et al. (study I) (1995)	Ek et al. (study II) (1995)	Ek et al. (study III) (1995)	Dyson* (1978)	Holmd, Nalden* (study I) (1974)	Holmd, Nalden (study Office et al. (1978)
Purpose	Because they assume massage therapy is effective in improving cellular immunity, they want to investigate if skin rubdown may also have similar effects.	To investigate if massage is associated with psychological and physiological responses after a 3-minute treatment by two persons with a 3-minute control period of undisturbed rest in institutionalised elderly.	To investigate if the effect of massage treatment compared with the effect of a 3-minute control period of undisturbed rest in institutionalised elderly.	Evaluating the effect of massage treatment compared with the effect of a 3-minute control period of undisturbed rest in institutionalised elderly.	To study the long-term effects of treatment on normal skin.	To study the effect of massage on normal skin immediately after massage.	To study the effect of massage on normal skin immediately after massage.	To investigate the effect of massage by pressure areas on blood flow in skeletal muscle.	To investigate the effect of massage by pressure areas on blood flow in skeletal muscle.	To investigate the effect of massage by pressure areas on blood flow in skeletal muscle.
Definition of massage as applied in each study.	Specific 45-minute massage protocol was designed for this study, based on Swedish, Thai, Pinyin, Acupressure and Craniofacial Therapy modalities.	A specific 45-minute massage protocol was designed for this study, based on Swedish, Thai, Pinyin, Acupressure and Craniofacial Therapy modalities.	Back rubs were administered during early evening hours by the same investigator.	A wet massage treatment of 30 seconds at eight localized areas, 3 times daily using a massage is performed for 60 minutes.	Small circular movements with the fingertips from the centre for 3 min, with liniment in an area of 10 cm ² .	Small circular movements with the fingertips from the centre for 3 min, with liniment in an area of 10 cm ² .	Small circular movements with the fingertips from the centre for 3 min, with liniment in an area of 10 cm ² .	Periosteal compression including kneading, squeezing and friction applied for 2 min.	Periosteal compression including kneading, squeezing and friction applied for 2 min.	Periosteal compression including kneading, squeezing and friction applied for 2 min.
Method	Skin rubdown using a dry towel to treat the whole body for about 10 minutes for 10 days.	Daily massage of 45 minutes for one month with caution to test if 11 persons of the whole blood pressure was too low or too high and skin shows dryness or increase of stress values.	Back rubs were given 3 times a day, Group 2: position change 3 times a day for a month.	Group 1: massage 3 times a day, Group 2: position change 3 times a day for a month.	The patients were measured over 2 days each to examine the effect of massage immediately after it was performed.	The patients were measured for 1 day of the systems were each on normal skin, rubbed and the other half was normally cared for (vasotonic, dried and lightly powered).	The patients were measured for 1 day of the systems were each on normal skin, rubbed and the other half was normally cared for (vasotonic, dried and lightly powered).	Skeletal muscle blood flow was measured before, during and after every application of periosteal compression on the forearm.	Skeletal muscle blood flow was measured before, during and after every application of periosteal compression on the forearm.	Skeletal muscle blood flow was measured before, during and after every application of periosteal compression on the forearm.
Sample	46 bedridden old patients (day-nose central stroke), older than 70 years.	15 females (6 men and 7 women) agreed to participate. Experimental group: n=12 (6 men), control group: n=7 (2 men). Mean age 70 years.	41 patients at risk of pressure sore, 15 or older. The patients were randomly assigned to one of the groups. Mean age = 63.57 (for each group: n=23 and 10).	41 patients at risk of pressure sore, 15 or older. The patients were randomly assigned to one of the groups. Mean age = 63.57 (for each group: n=23 and 10).	29 patients (15 women, 14 men) with normal skin who were at risk for developing pressure sores. Mean age: 77.1 ± 6.2 SD.	29 patients (15 women, 14 men) with normal skin who were at risk for developing pressure sores. Mean age: 77.1 ± 6.2 SD.	29 patients (15 women, 14 men) with normal skin who were at risk for developing pressure sores. Mean age: 77.1 ± 6.2 SD.	9 healthy volunteers, 22-32 year old.	9 healthy volunteers, 22-32 year old.	9 healthy volunteers, 22-32 year old.
Whom collected the data?	A licensed massage therapist.	A second investigator recorded physiological measurements.	Nurses and the investigator.	Nurses and the investigator.	The massage was given within each group by one and the same individual who was trained in the massage technique.	The massage was given within each group by one and the same individual who was trained in the massage technique.	The massage was given within each group by one and the same individual who was trained in the massage technique.	A professional physical therapist.	A professional physical therapist.	A professional physical therapist.
Whom performed the massage?	The nursing personnel.	The investigator.	Nurses.	Staff nurse.	The massage was given within each group by one and the same individual who was trained in the massage technique.	The massage was given within each group by one and the same individual who was trained in the massage technique.	The massage was given within each group by one and the same individual who was trained in the massage technique.	A professional physical therapist.	A professional physical therapist.	A professional physical therapist.

[illegible]

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Chapter 3

A systematic review of the efficacy of topical skin application of Dimethyl Sulfoxide on wound healing and as an anti-inflammatory drug.

Inge GP Duimel-Peeters, Ronald H Houwing, Coen P Teunissen,
Martijn PF Berger, Luc HEH Snoeckx, Ruud JG Halfens

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Background: Preceding our research about the evaluation of massage with a cream that contains dimethyl sulfoxide (DMSO) as a preventive method for pressure ulcers, a review study was completed. Articles on application of DMSO on the human skin in conditions where wound healing and/or inflammation characteristics are involved were included. **Objectives:** The literature was evaluated with respect to the efficacy of DMSO in different concentrations on wound healing and as an anti-inflammatory drug, administered by topical application to the skin. **Methods:** This systematic review was performed according to the rules of the meta-analysis. The authors searched for articles in MEDLINE, PUBMED, EMBASE-Excerpta Medica, the Cochrane Controlled Trial Register and Database for Clinical Reviews, and the Cochrane Skin and Wounds Group. **Conclusions** were made after blinded assessment of the methodological quality of the studies according to the standardized methodological criteria. Disagreements between reviewers were identified and subsequently discussed. If disagreements were not resolved, a fourth, blinded, expert reviewer would be consulted. **Results and Conclusions:** A review of the literature on experimental dermatological studies using DMSO revealed numerous studies using experimental animals. Dermatological studies with DMSO in humans have been scarce. Although the included studies were based on small samples and often lacked reference groups, the authors concluded that DMSO seems safe to use in concentrations less than 50 percent, either by rubbing or by spraying; DMSO in concentrations higher than 50 percent gives an increasing risk of side effects; and at concentrations below 50 percent, DMSO has favorable effects on inflammation and wound healing, as well as an analgesic effect.

Pressure ulcers, also commonly referred to as bedsores, pressure sores, decubitus ulcers or simply decubitus, can develop when sustained load, friction or shear is applied to localized areas of the body, leading to degeneration of the skin and underlying soft tissues. As in other countries, pressure ulcers form a major problem in Dutch institutions for health care services.⁽¹⁾ Various theories have been forwarded to explain the aetiology of pressure ulcers, with most experts adhering to the theory that pressure ulcers result from chronic occlusion of capillary blood flow, leading to alternating periods of ischemia and reperfusion. This process is associated with repetitive formation of reactive oxygen species (ROS) and concomitant tissue necrosis.⁽²⁾ Recently, pilot studies have revealed that rubbing the intact skin with a dimethyl sulfoxide (DMSO)-containing cream during the first stage of pressure ulcers according to the four grade system of the European Pressure Ulcer Advisory Panel (EPUAP), leads to a decrease in pressure ulcer occurrence among high risk patients.^(3,4)

DMSO ($(\text{CH}_3)_2\text{S-O}$) is a water-white to straw-yellow-colored organic liquid. It is an oily substance with a smell of sulfur and a slightly bitter taste. In topical application, this simple, highly polar chemical compound has been found to alleviate ischemic damage in several experimental animal models.^(5,6) In addition to an analgesic effect, the most important property of DMSO is the enhancement of percutaneous penetration.⁽⁷⁾ When used in combination with other substances, DMSO facilitates their diffusion through the stratum corneum of the skin, triggers the formation of deposits in the deeper layers of the subcutaneous tissue and promotes transport into the local blood vessels.⁽⁸⁾ Hence, dermatologists use it as a vehicle for other medication.

In pressure ulcer tissue, like any tissue in which inflammation occurs, repetitive ischemia-reperfusion episodes lead to the local formation of ROS. The main representatives of these radicals are the superoxide anion (O_2^-), hydrogen peroxide (H_2O_2) and the hydroxyl radical ($\text{OH}^\cdot$). Since DMSO is known to be a hydroxyl-inactivating compound, it can be assumed that its beneficial effects on pressure ulcers are based upon this activity.

The purpose of this review is to evaluate the literature on the efficacy of

DMSO in various concentrations on wound healing and as an anti-inflammatory drug, administered by topical application to the skin.

2 | Methods

A MEDLINE literature research was carried out covering the last 36 years (starting in 1966). At first, the search was determined on studies involving DMSO by one specific disorder, e.g., pressure ulcers. However, this did not yield enough articles, so the 'domain' had to be expended. The following keywords were used: dimethyl sulfoxide, clinical dermatology, pharmacology and toxicology, bio-penetrator, the skin, hydroxyl radicals, ROS, scavengers, treatment of ulcers, and inflammation. In addition, the references of all articles retrieved were further examined. The same search was done in PUBMED and EMBASE-Excerpta Medica. A last extensive search strategy was used in the Cochrane Library by means of the Cochrane Controlled Trial Register and the Cochrane Database of Clinical Reviews. Finally, the Cochrane Skin Group and the Cochrane Wounds Group were explored. Abstracts were not selected. One unpublished study was selected because of its relevance to the topic of the present review.⁽⁴⁾ Studies were only included if DMSO was applied locally on the diseased skin in conditions involving wound healing and/or inflammation, or on healthy skin in order to determine its sensitivity to various DMSO-concentrations. Research using experimental animals was excluded.

Table 1 lists the criteria used, which were weighed by three independent reviewers with different backgrounds (dermatology, pharmacy, and physiotherapy and movement sciences). Detailed information about these criteria is presented in Appendix 1. The criteria are not listed according to the generally accepted principles of intervention research but based upon the more detailed four general dimensions proposed by Feinstein⁽⁹⁾, Bouter⁽¹⁰⁾ and Assendelft et al.⁽¹¹⁾, to describe the quality of scientific publications. These four dimensions are the external validity, the internal validity, the method of data-presentation and data-analysis, and the good-clinical-practice-dimension (GCP), which cover over 19 methodological criteria (A-S). Each criterion was given a weight, the sum of which determined the quality for each dimension. The score on each dimension revealed the value of each article on each of these dimensions. This system reveals both the strong and weak points of each of the presented studies.

Table 1 | Dimensions of quality table; a criteria list for the methodological assessment of articles about the efficacy of DMSO on wound healing and as an anti-inflammatory drug, topically applied to the skin.

Dimensions of quality (criteria*)	Weight Factor
External Validity	30
a. Homogeneity: selection and restriction	3
b. Interventions included in protocol informative described	10
c. Relevant outcome measures	10
d. Adequate follow-up period	5
e. Description of side effects	2
Internal Validity	35
f. Pragmatic study	5
g. Placebo-controlled study	5
h. Adequate randomisation procedure / randomisation concealment	5
i. Blinded assessment of outcome measures	7
j. Comparability of relevant baseline characteristics	5
k. Drop-outs described for each study group separately	3
l. Co-interventions avoided	5
Data (presentation and analysis)	20
m. Adequate presentation of data for each study group	5
n. 10 subjects in the smallest group	1
10 - 20 subjects in the smallest group	3
20 subjects in the smallest group	5
o. Adjustment for confounding variables and/or differences at prognostic indicators at baseline	5
Good Clinical Practice (GCP)	7
p. Concentrations DMSO described	2
q. Application DMSO described	3
r. Informed consent of patients	1
s. Consent of medical ethical committee	1

* A more detailed description of the criteria is given in appendix 1.

Adapted from Assendelft WJJ, Scholten RJPM, van Eijk JTM, Bouter LM. De praktijk van systematische reviews III. Methodologische beoordeling van onderzoeken (The practice of systematic reviews. A methodological assessment of research). *Ned Tijdschr Geneesk* 1999;143(14):714-8

Appendix 1 | Details of criteria listed in table 1

External Validity

- Description of inclusion and exclusion criteria (2 points). Restriction to a homogeneous study population (1 point).
- Manipulative treatment explicitly described (5 points). All reference treatments explicitly described (5 points).
- Relevant outcome measures, which include the following: 1) healing of erythema; 2) healing of ulcers /flattening of the scar; 3) softening of the skin and subcutaneous tissue; 4) analgesic effects/pain relief; 5) less fluid formation; 6) increased blood flow; 7) positive effects on one or more inflammation-symptoms: rubor, dolor, tumor, calor; 8) histochemical changes (increased flow of ions); 9) increased range of motion of the affected part of the body (look for biological plausibility between the applied interventions and the outcome measures).
- Outcome of measures assessed during or just after the treatment (6 points). Outcome of measures assessed after 10 days or longer (4 points).
- Description of side effects (skin irritation, a 'garlic' breath odor, burning or pricking sensation of the skin, blister-formation, urticarial reaction) (2 points).

Internal Validity

- Comparison with an established treatment (5 points).
- Comparison with placebo (5 points).
- Randomisation procedure described (2 points). Randomisation procedure that excludes bias; for example, sealed envelopes (= randomisation concealment) (3 points).
- Each blinded measurement of the first seven measurements mentioned under point C earns 1 point.
- Comparability for duration of complaints, value of outcome measures (seriousness of complaints), age, recurrences, and sex (1 point each).
- Information about which group patients withdrew (2 points) from and reason for withdrawal (1 point).
- Other physical treatments or medical interventions are avoided in the design of the study (medication of no influence on the specific treatment or outcome measurements (4 points). If there were other interventions these were identical for all the groups (1 point).

Data (Presentation and Analysis)

- Frequencies or means and SD for each study group at intermediate (1 point) and final measurements (4 points).
- Smallest group immediately after randomisation (<10=1 point; 10 - 20 = 3 points; 20 = 6 points).
- Adjustment of results for confounding variables (differences of prognostic characteristics at baseline) by using multivariate analysis (5 points). This is especially important by non-experimental research. In case of experimental research, internal validity is guaranteed by the randomisation-procedure. Or, possible confounders were considered and were excluded (3 points).

Good Clinical Practice

- Description of the used amount of concentration DMSO (2 points).
- Description of how DMSO is applied to the patient (3 points).
- All patients agreed with the informed consent (1 point).
- There was a consent of the Medical Ethical Committee for the described study (1 point).

Scoring methods

All publications were blinded for author(s), journal and year of publication. The three reviewers independently scored all the criteria listed in Table 1 for each publication, using scores '+', '-' and '?', with the following meanings:

- +: Informative description of each of the above mentioned criteria; adequate study design and implementation (preventing bias).
- : Informative description, but inadequate study design or implementation.
- ?: Absent or insufficient information, or impossible to assign '+' or '-'.

The level of agreement between the reviewers was determined by calculating the inter-rater coefficient Cohen's Kappa K. A K-value higher than 0.75 was considered to indicate good agreement, while a value between 0.40 and 0.75 was considered to indicate reasonable agreement. Below $K = 0.40$, reviewers were considered to disagree. Upon identification of disagreement, a consensus meeting was organized. If disagreements could not be resolved, a fourth reviewer was to be consulted for a final independent judgment.

All methodological criteria rated '+' were scored using the weighting factors listed in Table 1. The assessments resulted in a hierarchical list for the four dimensions, determining the quality of a particular study/article. Higher scores indicated articles that provided more detailed description of the elements referred to in each criterion, for that specific dimension. Ranking the studies, according to their methodological quality, resulted in two scores; a total score without the good-clinical-practice-criteria ranging from 4 (poor) to 65 (good), and a second total score including the good-clinical-practice-criteria resulting in scores ranging from 7 (poor) to 71 (good). For the comparison of studies, the authors always applied the second score. An arbitrary cut-off point of 43 was chosen, which is 50% of the maximum total score when each criterion is totally fulfilled. Below this point studies were defined as of poor methodological quality.

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3 | Results

The literature search resulted in the identification of 27 publications of which 14 met the inclusion criteria. An overview of the characteristics of

these studies is given in Table 2. The overall quality of the majority of the studies was rather low (see Table 3⁽¹²⁻¹⁷⁾); only 5 studies received a total score exceeding 43 points (our cut-off point).

The three reviewers initially agreed on 216 of the 266 items (81%). On the average the inter-rater agreement coefficient Cohen's Kappa K between observers 1 and 2 was 0.654 (reasonable), while that between observers 1 and 3 was 0.736 (reasonable) and that between observers 2 and 3 was 0.887 (good). Nearly all disagreements were due to reading errors or to different interpretations of the methodological criteria due to the different backgrounds of the reviewers. Since the three reviewers were able to resolve all disagreements, a fourth reviewer was not consulted.

Most effects of treatment with DMSO reported in these articles were beneficial, both for wound healing and for analgesia. Three of the five studies that scored higher than the cut-off point emphasizes these effects.^(18,20,22) The favorable results of DMSO related first of all to its positive anti-inflammatory effects (with a few exceptions), followed by wound healing effects and very often pain relief. In a few cases, DMSO application was associated with the occurrence of more inflammatory signs than with the fact that wounds grew worse. The concentrations of DMSO varied from 5 to 100 percent with only one study expressing a preference for 5-percent DMSO.⁽⁴⁾ A positive correlation was found between the DMSO concentrations and the appearance of side effects. It should be pointed out that at DMSO concentrations below 50 percent (i.e. 10 % or 5 %), side effects were almost absent, while the positive effects were still obvious!

The criteria upon which patients were selected varied across the studies and were often inadequately described. In a few cases, the sample size was too small to allow reliable conclusions.

The design of the various studies was often inadequate (rated '-') in terms of loss to follow-up, sample size, randomisation procedure, or data-presentation. In 7 articles some kind of information was given regarding dropout rates. The number of patients using DMSO in each of the studies ranged from 2 to 315.

Despite these large differences, some trends could be detected in the outcome measures, the most frequently mentioned being reduction of erythema

and healing of ulcers, analgesic effects or pain relief, and positive effects on one or more inflammation symptoms such as rubor, dolor, calor and tumor. Negative effects of DMSO always involved deterioration of inflammation signs. The outcome measures are described in detail in Appendix 1. Of the 5 studies ranked highest, 4 studies (Lishner *et al.*⁵, Geertzen *et al.*¹⁸, Salim *et al.*²⁰, Binnick *et al.*²²) had high scores for relevant outcome measures. Other studies with only positive results also reached higher methodological scores. Only 5 articles mentioned the use of informed consent and approval by a medical ethics committee.

The ranking of the 14 studies remained unchanged when scores were calculated without the GCP-dimension. Except for the study by Geertzen *et al.*⁽¹⁸⁾, all studies scored relatively better on the external than on the internal validity criteria.

We also computed the inter-item correlations and performed reliability analyses. Of all dimensions, the GCP-dimension showed a low item-rest correlation ($r_{it} = 0.59$), which could be a reason to omit this item from further literature reviews. This conclusion was confirmed by the value of Cronbach's alpha for the total scale after deletion of this GCP item: the alpha value without GCP was 0.88, while the alpha value with GCP was considerably lower at 0.82. Omitting the GCP-dimension will probably raise the reliability. This conclusion is confirmed by the correlation matrix (see Table 4), which shows Pearson's correlation between GCP and the total score to be relatively low ($r = 0.64$) compared with the correlation between the other dimensions and the total score. The correlations between the external and internal validity values with the total score were highest.

Table 2 | Summary of studies (in order of ranking of Table 3) of the effects of DMSO on human skin and the efficacy of DMSO on wound healing and as an anti-inflammatory drug, topically applied to the skin.

Authors	Purpose	Method	Sample	Results/Conclusions
Salim, 1994. ²⁰	To investigate the effects of DMSO and allopurinol as co medication of cimetidine therapy in patients with refractory duodenal ulceration.	A prospective randomised double blind study whereby allopurinol and DMSO 50% were administered orally, 4 times a day for 8 weeks.	N = 315. No placebo group. Ages ranged from 19 to 71 years.	Positive effects of DMSO and allopurinol as co medication of cimetidine. Especially on wound healing. Objective measurements are restricted through the type of research (scopie).
Geertzen et al., 1994. ¹⁸	To evaluate the use of DMSO as an early treatment in patients with reflex sympathetic dystrophy (RSD).	One group (A) was treated with DMSO 50% 4 times a day for 3 weeks. The lotion with DMSO was applied with a brush on the affected hand. Group B received the RIS block twice a week for 3 weeks. (RIS = regional intravenous isemelin)	N = 26 > 21 years. No one had ulcers and wounds in the affected area or was pregnant. They had no other treatment before the start of the study. Results of treatment with RIS was compared with the results of treatment with DMSO.	Positive effects of DMSO on wound healing and as an analgesic; Statistics: Chi-square test.
Liehner et al., 1985. ⁵	To investigate the treatment of diabetic perforating ulcers with local DMSO.	In a prospective clinical trial DMSO 25% was applied every day for 20 min.. If the progress of healing seemed unsatisfactory the concentration of DMSO was raised to 50%. 20 weeks of therapy.	N = 40 (mean age = 65.5 years). Duration of diabetes mellitus ranged from 8 to 30 years. No placebo group and a too small population.	No conclusion with regard to wound healing effects or anti-inflammatory actions (patients with ulcers were excluded). Statistics: student t-test, but the meaning of it is doubtful.
Langendijk et al., 1993. ¹⁹	To investigate the effects of a 50%-DMSO cream as a treatment of acute RSD.	A prospective study in which a DMSO 50%-cream was applied 5 times daily.	N = 37. Selected by using a RSD-diagnosis protocol. Ages ranged from 10 to 77 years. No placebo group.	No description of wound healing effects. There are anti-inflammatory effects when you consider RSD as an inflammatory process. Statistics: student t-test for some parts.
Binnick et al., 1977. ²²	To investigate the effects of DMSO in the treatment of scleroderma.	Concentrations of 70% and 5% DMSO were compared. Painting and immersion techniques were used for evaluation.	N = 24 (19 with systemic scleroderma 5 with localized scleroderma)(30 - 65 years). Duration of the disease from onset of symptoms to inception into the study ranged from 2 to 18 years.	No effects on wound healing and inflammations. A positive analgesic effect was found.

Table 2 | Summary of studies (in order of ranking of Table 3) of the effects of DMSO on human skin and the efficacy of DMSO on wound healing and as an anti-inflammatory drug, topically applied to the skin.

Authors	Purpose	Method	Sample	Results/Conclusions
Van Rossum, 1997. ⁴	To investigate the treatment and prevention of pressure ulcers with DMSO.	Patients were treated locally with DMSO cream (5%) twice daily during an experimental period of 36 months. The surrounding intact skin of patients with open ulcers was treated the same way.	N = 39 (with first stage pressure ulcers). Age between 80 - 83 years. All the patients were first observed during a control period before the rubbing with DMSO started.	Very positive effects of DMSO on inflammation, if pressure ulcers are considered as such. Positive effects on wound healing. Statistics: student t-test.
Goris et al., 1986. ¹⁷	To investigate DMSO as a hydroxyl scavenger by RSD.	During a crossover study, DMSO 50% and a placebo were each locally applied 5 times a day for 1 week. Before and after each treatment, both the patient and the examiner as to clinical activity of RSD performed subjective evaluation, and measurement was performed of the range of motion of all joints in the affected extremity.	N = 20 (with RSD). No age mentioned. Each patient was treated with the placebo and with DMSO, the order was determined by randomisation.	The effects of DMSO are used to indicate that RSD is an inflammatory reaction!
Agner et al., 1989. ⁵⁶	A test for the assessment of sensitive skin. A quantification of DMSO-response.	DMSO 100% was applied during 5 minutes on a test area on the flexor side of the upper arm. Each person had DMSO applied to two test areas. Clinical grading of the skin response to DMSO was performed 5 min. after removal of DMSO.	N = 12 (mean age = 31.5 years). Informed consent was obtained as well as local ethical committee approval. For comparison, measurements were performed simultaneously on adjacent normal, unexposed skin.	No effects on inflammation. Statistics: Wilcoxon matched-pairs test.
Sulzberger et al., 1967 ⁷⁷	To investigate the effects of DMSO on human skin in vivo.	Observation of the in vivo effects of topical application of DMSO (10 - 90%) on intact skin. Determination of the route and depth of penetration of visual tracers to the intact skin with DMSO.	N = 64 healthy Caucasian males, physically normal and no medical history for allergy, organic disease and skin disorders. 5 subgroups with a strong variance in amount. No age mentioned.	No specific conclusion on effects on human skin, wound healing or as anti-inflammatory drug.
Frosch et al., 1980. ²⁰	To quantify the wealing response of the human skin to DMSO.	Concentrations of 90%, 95% and 100% DMSO were applied for 5 min. to circular areas 8 mm in diameter. Wealing was scored on a five-point scale after 10 min.	N = 200 students. Ages ranged from 18 to 30 years. No placebo group.	No specific conclusion on effects on human skin, wound healing or as anti-inflammatory drug.

Table 2 | Summary of studies (in order of ranking of Table 3) of the effects of DMSO on human skin and the efficacy of DMSO on wound healing and as an anti-inflammatory drug, topically applied to the skin.

Authors	Purpose	Method	Sample	Results/Conclusions
Alberts et al., 1991. ¹³	To investigate the effects of DMSO for mytomycin-C-induced skin ulceration.	DMSO, in 99% solution, was topically administered, twice daily.	Case report of only 2 patients (47 and 56 years old).	Promising effects of DMSO on healing of skin ulcers after infiltration of mytomycin-C. Anti-inflammatory effects.
Engel, 1967. ¹⁴	To describe the indications and contraindications of the use of DMSO in clinical dermatology.	DMSO (40 - 80%) was applied with cotton tipped applicators or by immersion 2 to 3 times daily. Where bilaterally similar lesions appeared, those lesions were treated only on one side, in order to obtain some form of control.	N = 45, divided in 3 groups of different dermatological disorders. No age mentioned.	No specific conclusion and no statistics. Psoriatic patients suffered more from inflammation by using DMSO.
Scherbel et al., 1967. ¹⁵	The relation between DMSO and the improvement of generalized scleroderma.	Each patient served as his own control inasmuch as previous treatment had been ineffective. DMSO (30 - 100%) was used for periods ranging from 3 to 23 months.	N = 42. Duration of the disease ranged from 1 to 25 years. All patients had varying degrees of systemic involvement. No placebo group. Ages ranged from 20 to 69 years.	No positive effects on wound healing. Anti-inflammatory effects were observed in the initial stage of treatment.
Engel, 1966. ¹⁶	To investigate the application of DMSO in clinical dermatology.	DMSO (40 - 80%), was applied with cotton tipped applicators or by immersion 2 to 3 times daily. Where bilaterally similar lesions, the lesions of one side were used as control.	N = 36. All patients had completed blood counts and urinalyses. Biopsies were taken before initiation of DMSO treatment and at the termination of treatment.	No specific conclusions were drawn.

A review of the literature on experimental dermatological studies of the controlled trial type using DMSO revealed numerous studies using experimental animals. In contrast, dermatological studies with DMSO in humans have been scarce. The reason for this is not clear because the application of DMSO on the skin is not dangerous, causing only some occasional small side effects like itching and skin irritation, tingling or burning sensations and a bad breath (garlic odour). One possible explanation for the small number of studies in humans could be publication bias. The sample sizes of patients in these studies are very often too small, resulting in non-significant results, whether negative or positive.

The present literature search was undertaken to find out whether or not DMSO application could be effective in the treatment of pressure ulcers. Although various shortcomings of the studies that were reviewed blurred a clear conclusion on the efficacy of DMSO, we were able to identify sound results in 7 studies. The most important effects appeared to be anti-inflammatory effects, wound healing effects and pain relief. The 7 remaining studies recommended the use of DMSO, but did not provide sufficient information to allow reliable conclusions. The most important conclusion of the present review is that DMSO is effective as an anti-inflammatory and analgesic agent with positive effects on wound healing at concentrations equal to or larger than 5 percent. Furthermore, the treatment has to be continued for a minimum period of one week, and DMSO has to be applied two to three times a day. The main advantage of such a low concentration is that side effects are almost absent.

It is not clear if there are significant differences between various modes of application, e.g., spraying or rubbing, in the wound healing or anti-inflammatory effects. This was not investigated. We should bear in mind that rubbing introduces an additional variable, which could possibly affect inflammation, wound healing and pain relief.

In most of the studies, the intervention programme was implemented without the necessary relevant reference or placebo treatment. This prevented us from evaluating methodological quality of randomized, controlled trials,

Table 3 | Summary of the methodological assessment for each criterion of the four different dimensions of quality

Dimentione	External Validity					Internal Validity					DPA					GCP					Total Score 80 without GCP*	Total Score 87 with GCP*
Criteria	a	b	c	d	e	f	g	h	i	j	k	l	m	n	o	p	q	r	s		(p,q,r,s)	(p,q,r,s)
Max Weight	3	10	10	5	2	5	5	5	7	5	3	5	5	5	5	2	3	1	1			
Study																						
Salim ¹⁶	3	10	7	5	2	5	2	5	5	4	3	3	3	5	3	2	2	1	1		65	71
Geertzen, et al. ¹⁶	2	6	7	3	1	4		3	5	3	3	5	5	3		2	2	1	1		50	56
Liehner, et al. ¹⁵	3	8	8	5	2	4	3	3	1	2	2		2	3	3	2	2				49	53
Langendijk, et al. ¹⁹	3	7	3	4	2	3				3	1	3	2	5	3	2	3	1			39	45
Binnick, et al. ²²	1	6	6	5	3	3	1	2	1	4		1	1	1	3		2	3	1		38	44
Van Rossum ⁴	3	6	4	4	1	4				4		4	4			2	3				34	39
Goris, et al. ¹⁷	1	5	4	1	2	2	2			2	1	2	2	3		2	2	1	1		27	33
Agner and Serup ¹⁸	2	5	3	4	1	1							4	3	1	2	3	1	1		24	31
Sulzberger, et al. ⁷	2	3	8			3							1	2		2	3				19	24
Froech, et al. ²¹	1	3	2		2											2	3				8	13
Alberts and Dorr ¹⁵			5	3	1	1										2	2				10	14
Engel ¹⁴		2	2	2	1					1						1	1				8	10
Scherbel, et al. ¹²	1	1			1					1			3			1	2				7	10
Engel ¹⁰			2		1								1			1	2				4	7
Mean	14.36					8.21					4.71					4.86					27.28	32.14
Std. Deviation	7.75					8.86					3.79					1.46					19.18	20.08

*GCP = Good clinical practice; *DPA = Data presentation and analyses

which we would have preferred to do in order to avoid conclusions based on trials of inferior methodological quality. We therefore decided to evaluate the studies that were included according to four dimensions instead of one methodological scale.

Furthermore, a considerable amount of information, that would have been relevant to the evaluation of the methodological quality, seemed to be missing. An adequate description of the randomisation procedure is very important, as randomisation/matching is necessary to prevent selection bias. An adequate description of such randomisation was provided in only 4 of the articles, while 3 others gave some information. It should be pointed out that even the use of an adequate randomisation procedure does not guarantee equal distribution of prognostic factors and confounding variables among the study groups, particularly if the groups are relatively small.

Table 4 | The correlation matrix.

	External Validity	Internal Validity	Data Presentation and Analyses	Good Clinical Practice	Total Score
External Validity	1				
Internal Validity	.843	1			
Data Presentation and Analyses	.818	.760	1		
Good Clinical Practice	.610	.466	.673	1	
Total Score	.957	.944	.889	.641	1

Information about the participants and baseline values of outcome measures was indicative of the success of the randomisation procedure. Seven articles reported at least some of the baseline characteristics. Six articles provided a description of co-interventions.

Almost all the articles (13 of 14) presented relevant outcome measures of which pain relief and less dolor as an inflammation symptom differed from patient to patient because of its subjective character, but only 2 of the studies had applied a blinded assessment to them.

Thirteen articles reported side effects. Although side effects were often considered to be moderate or mild in the studies evaluated here, a small number of participants discontinued application of DMSO because of adverse reactions.

This review did not include an assessment of the quality of the outcome measures as the outcome measures included in our criteria list for methodological assessment of these studies could not be ranked in a priority list. Our list included the most important ones based on literature findings; most of these measures probably have been designed on the basis of face validity. The studies reviewed were given one point for each outcome measure reported. Only 5 articles mentioned the presence of an informed consent procedure and approval by a medical ethics committee. One article mentioned the presence of an informed consent procedure only.

The interpretation of the efficacy of DMSO depends partly on information on the use of co-interventions and the participants' adherence to the treatment regimen. As mentioned above, 6 articles described the use or absence of co-interventions; the others presented little information about the use of co-interventions. Seven articles described dropout rates.

Although the studies were based on small samples and often lacked reference groups, we can conclude that it seems safe to use DMSO on the human skin, either by rubbing or by spraying. The indication is to use DMSO in concentrations less than 50 percent because of the increasing risk of side effects at concentrations exceeding 50 percent. At concentrations below 50 percent, DMSO has favorable effects on inflammation and wound healing, as well as an analgesic effect, which is of course also an important aspect for the patient.

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Chapter 4

Massage to prevent pressure ulcers: knowledge, beliefs and practice. A cross-sectional study among nurses in the Netherlands, in 1991 and 2003.

Inge GP Duimel-Peeters, Mirjam A Hulsenboom, Martijn PF Berger, Luc HEH Snoeckx, Ruud JG Halfens

Background: Pressure ulcers are a major problem in all areas of health care in the Netherlands. National guidelines for the prevention and treatment of pressure ulcers were originally developed in 1985, and revised in 1991 and 2002. The value of these guidelines can be questioned because it seems there are not in line with the beliefs and practice of the caregivers, and not all of them are evidence-based. Aims and objectives: To get a better insight into nurses' current knowledge, beliefs and performed practices relating to massage, a study was designed to assess changes in these three aspects after the publication of the 2002 Dutch national guidelines. The outcome was compared to the situation in 1991. Design and Method: A cross-sectional comparative study was designed using written questionnaires. Questions were formulated regarding knowledge, and beliefs about prevention methods and the actual use of these methods in the prevention of pressure ulcers. The 2003 survey population consisted of nurses working in the Netherlands and was approached at random via subscriptions to Nursing News (i.e. Verpleegkunde Nieuws), a Dutch professional journal or via affiliations to an institution participating in the 2003 Dutch National Prevalence Survey of Pressure Ulcers. Results and Conclusions: Compared with the 1991 findings, the 2003 results show an improvement for the topic of pressure ulcers, but a deterioration regarding dehydration. It is obvious that the knowledge of the current CBO-guidelines on massage is still not widely distributed as it should be. Our overall conclusion is that the differences in responses between 1991 and 2003 are significant, and suggest that the nurses were better informed in 2003. Relevance to clinical practice: For the improvement of health care in the domain of pressure ulcer preventions, we need more than an accurate implementation of new or existing guidelines. Guidelines should also be based on qualitative, methodological well designed studies to be evidence-based.

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Pressure ulcers (PU) are a major problem in all areas of health care in the Netherlands.⁽¹⁾ Estimations for 1998 revealed that more than 1% of the total health care budget was spent on prevention and treatment of pressure ulcers. These ulcers are a common and painful condition among immobilised and debilitated patients and cause a great deal of suffering and frustration, not only to the patients themselves but also to their relatives and caregivers.⁽²⁾

Although various preventive measures are being used by nurses and caregivers^(1,3,4), what is used in practice does not necessarily correspond to what is theoretically recommended.^(5,6) In order to bring more structure in the nursing practice, Dutch experts have collated their relevant knowledge in this domain into national guidelines for the prevention and treatment of pressure ulcers. Originally developed in 1985, these guidelines were revised in 1991, and once again in 2002.^(4,7,8) In recent years, the attention paid to the problem of pressure ulcers has increased steadily as a result of the annual Dutch prevalence registrations, several publications in professional journals and last but not least, improved pressure ulcer consultancy in health care institutions.^(2,9,9,10)

In spite of all these efforts, some contradictory beliefs about the use and benefits of preventive methods persist in guidelines, practice and the literature. One of the commonly applied preventive methods is massage, which is described in national and international guidelines for the prevention of pressure ulcers as 'not useful'.^(3,4,8,11) Nevertheless, a survey held in Dutch hospitals shows that almost all nurses evaluated massage as an effective method, which was a reason for them to go on applying this treatment.⁽⁵⁾ Comparable results were found among health care workers in nursing homes.⁽¹⁰⁾

This example shows that the national guidelines do not correspond to nurses' beliefs. In addition to this, a recent literature study about the effectiveness of massage in the prevention of pressure ulcers shows that the number of studies on this topic is very limited and that the existing studies are often of poor methodological quality.⁽¹²⁾ Therefore, the tendency to adopt these guidelines in practice could be very limited.

In order to examine nurses' current knowledge, beliefs and performed practices relating to massage, a study was designed to assess changes in these three aspects after the publication of the 2002 national guidelines (as drawn up by the Dutch Institute for Healthcare Improvement⁽⁴⁾). The outcome was compared to the situation in 1991, the year in which the previous guidelines were published.^(4,13) We also explored whether changes in knowledge and/or beliefs had had any effect on everyday practice.

2 | Guidelines on massage

The 1991 and 2002 Dutch CBO-guidelines classify the techniques or methods to prevent the development of pressure ulcers into two groups i.e. 'useful' and 'not useful'. Both sets of guidelines describe skin massage as not useful for the prevention of pressure ulcers, but beneficial for the prevention of dehydration.^(4,8) The Belgian guidelines are also explicit on this point: 'Do not perform any kind of skin massage on pressure points, not even with ice'.⁽¹¹⁾ In its statement on Pressure Ulcer Prevention the National Pressure Ulcer Advisory Panel of the U.S. confirmed that cleaning and moisturising all skin surfaces is important and that aggressive massage should be avoided in order to prevent tissue damage.⁽¹⁴⁾ The European Pressure Ulcer Advisory Panel states: 'Avoid excessive rubbing over bony prominences as this does not prevent pressure damage and may cause additional damage'.⁽¹⁵⁾ Finally, the U.S. Agency for Health Care Policy and Research is positive about the use of creams and oils to prevent dry skin but advises against massaging the skin over bony body parts. Massage may squeeze and damage the tissue under the skin and make the patient more prone to develop pressure ulcers.⁽³⁾

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3 | Research questions

The present study tried to answer the following questions:

Regarding knowledge:

What do nurses know about the use of massage as described in the 2002 CBO guidelines?

Regarding beliefs:

Would nurses still like to use massage to prevent pressure ulcers in patients at high-risk of such ulcers?

Regarding practice:

Do nurses actually administer massage to prevent pressure ulcers in patients at high-risk of such ulcers?

Has there been a change in knowledge, beliefs and practice relating to massage between 1991 and 2003?

4 | Methods

Design

A cross-sectional comparative study was designed using written questionnaires among 529 nurses. Questions were formulated regarding knowledge and beliefs about prevention methods and the actual use of these methods in the prevention of pressure ulcers.

Measurement Instrument

The present survey (2003) used a written questionnaire, comparable to that of 1991, to collect the data.⁽⁵⁾ The 2003 questionnaire was divided into 7 themes. For our analysis, we used only the first 4 themes, which were the same as those used in 1991, i.e.:

(1) *General questions* concerning age, sex, education, work experience, and work situation;

(2) *Questions regarding practice*: respondents were presented with a list of preventive methods and were asked to indicate which ones they used in practice. Only the following 2 items were used for analysis: 'massaging the skin' and 'smearing the skin with local agents to prevent dehydration'. Answering categories were 'always', 'sometimes' and 'never'.

(3) *Questions regarding advice*: respondents were presented with the same list of preventive methods, but were now asked to indicate which methods they would recommend to prevent pressure ulcers. The same 2 items referred to above were used for analysis, with the same 3 answering categories.

(4) *Questions regarding knowledge:* respondents were presented with the same list of preventive methods, and were asked to evaluate each preventive method in terms of its being 'useful', 'sometimes useful' or 'not useful'; they could also indicate that they did not know whether a method was useful or not. Again, only the 2 items mentioned above were used for the analysis. Other preventive methods were not included in the analysis because they either had nothing to do with massaging, rubbing, or smearing or were not included in the CBO-guidelines to which we wanted to refer.

Three additional questions dealt with aspects of the policy on pressure ulcers in place at the nurses' institution, the availability of nursing journals at their ward, opportunities to participate in training courses and finally, questions regarding the awareness of the new 2002 CBO guidelines. Our analyses focused on the outcomes of massage for pressure ulcers and compared these outcomes with those of smearing the skin to prevent dehydration.

Population

The 2003 survey population consisted of nurses and other health care providers working in the Netherlands. The survey sample consisted of a total of 2536 persons, 976 of whom were approached at random via their subscription to *Verpleegkunde Nieuws* (Nursing News), a Dutch professional journal for nurses which has 20.000 subscribers. Another 1560 nurses were selected at random via their affiliation to an institution participating in the 2003 National Prevalence Survey of Pressure Sores.⁽¹⁶⁾ At first, 1332 questionnaires were returned (511 by *Verpleegkunde Nieuws* subscribers (52.35% response rate) and 821 by employees of institutions (52.62% response rate)). Of these 1332 questionnaires, 1140 (85.6%) met our inclusion criteria, which consisted of being involved in direct patient care and not working on more than one ward of the same institution. Of the 1140 questionnaires, 74 were not or only partially completed. Eventually, of the remaining 1066 (80.6%) questionnaires, 529 were used for final analysis because the respondents had an educational background and working environment that was comparable to that of the nurses in the 1991 survey. The working environ-

ment of all 529 respondents in 2003 (all registered nurses) is given in Table 1, while Table 2 shows the working environment of the participants of the 1991 survey. (Categorical hospitals are hospitals providing one specific medical specialization.)

Institution	Frequency (N=529)	Percent
Academic Hospital	73	13.8
General Hospital	451	85.3
Categorical Hospital	5	0.9

Table 1 | Distribution of the 2003-respondents in terms of working environment.

Institution	Frequency (N=529)	Percent
Academic Hospital	74	19.8
General Hospital	289	77.5
Categorical Hospital	10	2.7

Table 2 | Distribution of the 1991-respondents in terms of working environment.

The 2003 population consisted of 83.7% women (i.e., 443 women, with 1.7% missing data for the 529 respondents); versus 88.5% in 1991 (i.e., 330 women, with 0.3% missing data for the 373 respondents). The mean age in 2003 was 35.5 years compared to 32.5 in 1991 (0.5% missing data for 373 respondents).

5 | Results

Table 3 presents the 1991 and 2003 results as regards practice, beliefs and knowledge relating to massage to prevent pressure ulcers and smearing the skin to prevent dehydration. First of all, the results show a dramatic and significant change in practice, beliefs and knowledge in this respect. Whereas in 1991, almost all nurses (87.4%) reported that they 'always' or 'sometimes' used massage, this percentage had been reduced to 48.9% in 2003.

Although this is a remarkable reduction, it should be noted that this means that almost one in two nurses (48.9%) still used massage as a preventive method for pressure ulcers in 2003. Comparable results were found for the beliefs and knowledge relating to the use of massage for preventing pressure ulcers.

The knowledge, beliefs and practice relating to smearing the skin with local agents to limit dehydration had also changed, but not as dramatically as those for massage to prevent pressure ulcers. Here, a shift had occurred between the 'always' and 'sometimes' categories, in the sense that in 2003 more nurses used smearing 'sometimes', while in 1991 more nurses used it 'always'. All differences between 1991 and 2003, for both methods, were statistically significant ($p < .0001$, using t -tests for independent samples).

Possible influences of sex, age, years of work experience and working environment on the practice, beliefs and knowledge relating to massage to prevent pressure ulcers and dehydration were analysed for 1991 and 2003 using the Mann-Whitney and Kruskal-Wallis tests. For 1991, a significant relation was found between smearing the skin to prevent dehydration and the number of years of work experience ($p = .019$). A significant relation was also found between the belief that massage is useful to prevent pressure ulcers and the respondents' sex ($p = .019$). For 2003, significant relations were found between the practice of smearing the skin to prevent dehydration and the respondents' ages ($p = .007$) and working environment ($p = .022$). There was a significant difference between men and women as regards the belief that smearing the skin is useful to prevent dehydration ($p = .010$). Finally, a significant difference was found between the various ages as regards knowledge about massage to prevent pressure ulcers ($p = .038$). Table 5 summarizes all findings.

Because it was impossible to categorise the data into equal intervals, we used the Spearman correlation coefficient instead of the usual Pearson correlation coefficient, to assess possible relationships between variables. Spearman correlations were calculated to assess whether the 2003 survey data showed a relation between actual practice on the one hand and beliefs and knowledge on the other. The relation between use of massage and the

belief that massage is useful to prevent pressure ulcers yielded a Spearman correlation of 0.537, which was comparable to that for 1991 (0.539). The 2003 relation between *use of massage and knowledge about massage* for the same purpose yielded a Spearman correlation of 0.492, against 0.500 in 1991. Finally, the strongest relation, in 2003 as well as 1991, was that between the *belief that massage is useful and knowledge about massage* for the prevention of pressure ulcers: 0.655 and 0.666, respectively. The correlations for the other purpose, preventing dehydration by smearing the skin, are summarised in Table 4.

	2003					1991				
	Always	Sometimes	Never	Don't know	Missing	Always	Sometimes	Never	Don't know	Missing
Message to prevent PU	Practice	4.5	44.4	50.3	n.a.	0.8	31.6	11.0	n.a.	1.6
	Belief	19.8	45.4	33.6	n.a.	1.1	24.1	3.8	n.a.	2.9
	Knowledge	18.1	39.5	35.5	6.2	0.6	25.5	1.9	1.9	3.5
Smearing to prevent dehydration	Practice	18.3	66.4	14.7	n.a.	0.6	27.1	7.8	n.a.	1.9
	Belief	36.3	46.3	16.6	n.a.	0.8	24.7	4.0	n.a.	3.5
	Knowledge	35.5	43.5	13.2	6.6	1.1	32.2	3.2	3.2	2.9

Table 3 | Summary of the 2003 and 1991 answers (percentage) to questions regarding massage for preventing PU and dehydration.

	Spearman Correlation			Spearman Correlation	
	2003	1991		2003	1991
Message to prevent PU			Smearing to prevent dehydration		
Practice - Belief	.537	.539	Practice - Belief	.528	.482
Practice - Knowledge	.492	.500	Practice - Knowledge	.387	.446
Belief - Knowledge	.655	.666	Belief - Knowledge	.492	.550

Table 4 | Summary of Spearman correlations relating to prevention of PU and dehydration through massage and smearing.

	2003						1991					
	Pressure Ulcers			Dehydration			Pressure Ulcers			Dehydration		
Relation with:	Practice	Belief	Knowledge	Practice	Belief	Knowledge	Practice	Belief	Knowledge	Practice	Belief	Knowledge
Sex	.999	.454	.271	.654	.010	.796	.253	.019	.398	.855	.224	.081
Age	.971	.085	.038	.007	.452	.250	.764	.486	.861	.459	.792	.803
Years of work experience	.234	.138	.091	.072	.247	.081	.698	.345	.365	.019	.569	.345
Working environment	.165	.693	.931	.022	.291	.207	.688	.205	.422	.640	.484	.730

Table 5 | Influences of sex, age, years of work experience and working environment on practice, beliefs and knowledge relating to massage, to prevent pressure ulcers and dehydration (expressed as p-values).

Compared with the 1991 findings, the 2003 results show a positive development for the topic of pressure ulcers, but a deterioration regarding dehydration. It is obvious that the awareness of the current CBO guidelines on massage is still not widely distributed. There was a large variance in the frequency of the answers relating to knowledge. More than one third of the nurses (39.5%) reported that they thought that massage is sometimes indicated for high-risk patients. Findings in terms of actual use in practice were comparable, in that a large part of the group (44.4%) reported that they sometimes applied massage to prevent high-risk patients developing pressure ulcers, although only 4.5% said that they always used this method.

The current expert opinion is that massage as a preventive treatment for pressure ulcers could be harmful to underlying tissues.^(12,17,18) From our survey, it seems that this knowledge has insufficiently reached the wards. Patients are still being treated with what according to the CBO guidelines are non-useful interventions, and are undergoing possibly harmful treatments. However, it must also be pointed out that the results about the possible damage caused by massage are still not significant. Further research, supported by statistically proven quantitative data, is therefore strongly recommended.⁽¹²⁾

In the 1991 survey, 55.8% of the nurses always applied massage to patients at high risk of developing pressure ulcers. Another 31.6% reported massaging sometimes, which means that at that time only 11.0% may have been aware of the CBO guideline when they said that massage should never be performed. In 2003, it seems at least that nurses on the ward no longer consistently apply massage to every high-risk patient. It is questionable, however, whether this is entirely the result of awareness of the new CBO guidelines, in view of the rather large percentage of nurses (44.4%) who still apply massage in some cases. A possible alternative explanation for not 'always' massaging may be the increased workload, as it is generally accepted that the workload for nurses in the type of health care centres included in our survey has increased considerably over the last 5 years.

Compared with 1991, fewer nurses in the 2003 survey said they believed

in massage (19.8% versus 69.2%), while more reported not believing in massage (33.6% versus 3.8%), and 45.4% believed that massage is sometimes useful. Apparently, opinions among both believers and non-believers were stronger in 1991, as 45.4% of the 2003 respondents answered 'sometimes'. This could be a result of increased workload, or of doubt, or of more individual patient-oriented health care.

The 2003 survey results suggest that nurses had become more aware of the content of the CBO-guidelines on massage since 1991. Of the respondents in the 2003 survey, 18.1% reported that massage was regarded as a useful method - which it is not - against 67.3% in 1991. But the 2003 data also show that more nurses (6.2%) admitted not to know exactly what the CBO guidelines recommend than in 1991 (1.9%). Although at first sight, it thus seems that 2003 scores were 'better', a large part of the 'always'-group had shifted to the 'sometimes'-group, which again could be a result of increased doubt or of more patient-oriented health care.

The computed Spearman correlations are all relatively low with the exception of those between believing in massage and knowledge about massage, both in 2003 and 1991. Although in 2003, 19.8% of the nurses tended to believe in the beneficial effect of massage, only 4.5% actually applied massage in practice. This may have been due to work load but could also mean that more nurses did not apply massage in practice (50.3%), while only 33.6% were prepared to admit that they did not believe in the technique. The same conclusion can be drawn for the correlation between applying massage in practice and knowledge about massage. In 2003, more nurses reported never using massage (50.3%), while only 35.5% said they knew that massage is not useful. The highest correlations were found for the variables knowledge and belief: 0.655 for 2003 versus 0.666 for 1991. Apparently, it is more obvious to detect some correlation between the two 'theoretical' questions, i.e. those on belief and knowledge, than between one of them and actual practice. This could confirm our conclusion that it is not only evidence-based knowledge and belief that determine what happens in practice, but that other variables are also involved such as the influence of traditional knowledge, the personal- and team involvement, the familiarity with guidelines and the used

implementation-strategy through the management-teams.⁽¹⁹⁾ A very important variable, from personal perspective, seems to be the increased workload in recent years which is a major subject in the current debate on quality of care.

The opposite conclusions can be drawn as regards the nurses' attitude about skin smearing for the prevention of dehydration, which is defined by the CBO guidelines as a useful method. Knowledge about this appears to have been better in 1991 than in 2003. In 1991, 58.4% of all respondents answered that they knew that smearing the skin is always useful to prevent dehydration, while 63.3% also reported that they always used this method. In 2003, 35.5% of the nurses said they knew that smearing for this purpose was useful, whereas only 18.3% actually applied it. Again, the differences in practice may have been influenced by the increased workload. Our findings suggest that nurses are well aware of some of the contradictions concerning the practice of massage, as well as of the debate on this topic in the scientific world, but that they are not able to put their finger on it. This could explain the sometimes unexpected shifts in behaviour.

Some methodological issues regarding the present study must be addressed. First, there may have been some information bias. Using a questionnaire instead of observations means that it is not clear whether the answers accurately represent reality. Although the questionnaire was anonymous, it is possible that respondents may have given so-called 'socially desirable answers' or at least what they thought were socially desirable answers. This could explain the high frequencies of 'sometimes' answers, indicating that respondents do not really know what to answer (the answer 'do not know' was not always an option). The assumption that the answers reflect actual reality may have consequences for the validity of the conclusions. Furthermore, we assume that the N as well as for the 1991-survey as for the 2003-survey is large enough to overcome any possible sampling bias.

An important comment must further be made regarding the terms 'massaging the skin' and 'smearing the skin'. It is not always fully clear what people mean by these terms, neither in the literature, nor on the wards, nor in our questionnaires. It is possible that nurses report smearing patients' skin to

prevent dehydration but actually mean massaging or rubbing the skin, and vice versa. The CBO guidelines themselves also fail to provide specific definitions of these terms.

The findings of this study show a gap between theory and daily practice in the care of patients prone to pressure ulcers. The literature mentions several factors that may explain this gap. Kitson *et al.*⁽²⁰⁾ divided these factors into three categories, namely evidence, context and facilitation. Berwick⁽²¹⁾ used these factors in comparable categories: perceptions of the innovation, characteristics of individuals, and contextual factors. In the present case, one factor which could have caused the gap could be the evidence upon which the Dutch CBO guidelines are based. Although the 2002 CBO guidelines are more evidence-based than previous guidelines, only 5% of the guidelines are really evidence-based.⁽²²⁾

Another factor could be the degree of facilitation. Although the guidelines have been sent to all health care institutions, and reported in professional journals, there may have not been enough active facilitation within the institutions. Berwick⁽²¹⁾ stated that simple innovations spread faster than complicated ones, and guidelines often represent an overview of the state of the art, with a large number of recommendations. Reducing the recommendations to, for instance, the two or three most relevant ones, might considerably speed up adoption. The context, for instance in terms of an innovative culture, is also important. Buss *et al.*⁽¹⁹⁾ showed that the contextual factors in Dutch nursing homes do not facilitate the adoption of pressure ulcers guidelines.

Finally, it would be of great interest to examine the situation regarding this issue in other countries. As mentioned earlier, the EPUAP guidelines and the national Dutch guidelines both agree that massage is not useful. Therefore, it might be useful to know what the actual practice regarding pressure ulcer prevention is like in other European countries. Research about the relation between national guidelines and actual national performed practice could give us more insight into the effectiveness of guideline implementation strategies and their influence on practice.

7 | Conclusion

Our overall conclusion is that the differences between the responses to our questionnaires on massage to prevent pressure ulcers in 1991 and 2003 are significant, and suggest that the nurses were better informed in 2003. The greatest shift in frequencies was that from the 'always using massage' to the 'sometimes using massage' category. Since implementation requires a match between the perception of guidelines, the context and the adopters, the new guideline could have influenced this result positively. However, other factors may also have intervened, such as the context, the adopters and the way guidelines have been presented.

Although implementation of guidelines is an important topic and further research is needed for an understanding of effective strategies; further improvement of health care in the domain of pressure ulcer preventions requires more than accurate implementation of new or existing guidelines. Guidelines should also be evidence-based, that is based on qualitative, methodologically well designed studies. There is thus a need for more studies of this kind. In addition, there is also a need for good definitions of the terms 'massage' and 'skin smearing' to ensure that the answers to questionnaires really reflect what happens in practice.

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Chapter 5

Policy, knowledge and practice of massage to prevent pressure ulcers in relation to the Dutch prevalence rates.

Inge GP Duimel-Peeters, Martijn PF Berger, Luc HEH Snoeckx,
Ruud JG Halfens

Background: Pressure ulcers form a major painful and costly problem in all health care institutions in the Netherlands. Several activities have been undertaken to reduce the prevalence- and incidence rates of pressure ulcers. Regarding massage, (inter)national guidelines claim that the use of massage is not effective in pressure ulcer prevention. Nevertheless, massage is still a widely used tool for the prevention of pressure ulcer development. Previously, we found that nurses' knowledge and practice of massage is still not completely in accordance with the prescribed national guidelines. However, the last decade, there is a positive tendency in the nurses' awareness of the pressure ulcer prevention guidelines. Aims: We hypothesized that nurses their knowledge regarding massage will be positively related to their practice. Furthermore, we expected an interaction between this knowledge and the guided pressure ulcer policy of their institution. And finally, we wanted to find out whether institutions, the nurses of which still use massage, will have higher pressure ulcer prevalence rates. Methods: For this study, secondary analyses were performed on the data-sets of two studies of 2003, i.e. the Dutch National Pressure Ulcer Prevalence Survey and the 2003 cross-sectional study on knowledge, beliefs and use of preventive methods for pressure ulcer development among Dutch nurses. We used only data from institutions participating in both studies. Furthermore, data was aggregated on hospital-level, and patient populations were standardized by using only those patients at high risk for developing pressure ulcers. Results and conclusion: It can be concluded that neither knowledge nor practice is related to pressure ulcer prevalence rates, and that only 2 out of the 11 quality indicators determining the pressure ulcer policy, showed a slightly positive relation with the registered prevalence rate. However, there was a sound relation between nurses' knowledge and their performed practice. But whether their opinion was to belief in the usefulness of massage or not or whether they perform massage or not, no confirmed indications exist that any argument whatsoever influences the prevalence rates.

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Pressure ulcers (PU) form a major painful and costly problem in all health care institutions in the Netherlands.⁽¹⁾ Several activities have been undertaken to reduce the prevalence- and incidence rates of pressure ulcers. On the institutional level guidelines were adopted or written, nurses specialised in pressure ulcer prevention were appointed, and courses about the prevention and treatment of pressure ulcers were introduced. Although nurses and other health care givers use various methods to prevent the development of PU, little is known about the general evidence-based effects of these measures. The methods used in practice do not necessarily correspond to what is theoretically recommended.⁽²⁻⁵⁾ One of the commonly applied methods is massage. In national as well as international guidelines for the prevention of PU, such as the Dutch guidelines, the guidelines of the U.S. Agency for Health Care Policy and Research / National Pressure Ulcer Advisory Panel, and the European Pressure Ulcer Advisory Panel, massage is described as not being useful.⁽⁶⁻⁹⁾

In general, guidelines are detailed and complex, and contain a lot of recommendations. As stated by Berwick⁽¹⁰⁾, it is important to reinvent an innovation such as a guideline, and simplify it to the main recommendations. During the implementation-process however, the question arises whether it is necessary to pay attention to the recommendations concerning the use of non-effective methods.

In this study, it will be investigated if it is desirable to pay additional attention to massage which is considered to be such a non-effective preventive method. Therefore, the relations between institutional rules regarding PU prevention, individual knowledge and performed practices of the nurses concerning PU prevention, and PU prevalence rates on institutional level, were investigated. In Figure 1, the model with assumed relations between the different features, i.e. PU-policy, knowledge, practice and prevalence rates is shown.

Figure 1 | Model of the assumed relations between PU-policy, knowledge, practice and PU prevalence rates.

It was expected that there exists an interaction between the knowledge of nurses regarding massage and the policy of their institutions. Nurses working in institutions with a well defined PU-policy were expected to have knowledge regarding massage in accordance with the prescribed national guidelines. Furthermore, it was also hypothesized that nurses' knowledge regarding massage is positively related to their practice. Finally, it was expected that institutions, the nurses of which still use massage will have higher PU prevalence rates.

2 | Research questions

The present study will provide answers to the following questions:

1. Is the pressure ulcer-policy of an institution, measured by the presence of 11 quality indicators, related to the knowledge (whether or not in accordance with the prescribed national guidelines) of nurses regarding the use of massage to prevent pressure ulcers?
2. Is the nurses' knowledge regarding the effectiveness of the use of massage to prevent pressure ulcers related to their actually performed practice?
3. Is nurses' performed practice related to the measured pressure ulcer prevalence rates?
4. Is there a relation between the institutional PU-policy and their prevalence rate?

For this study, secondary analyses were performed on the data of two studies of 2003, i.e. the Dutch National Pressure Ulcer Prevalence Survey⁽¹¹⁾ and the 2003 cross-sectional study on knowledge, beliefs and use of preventive methods for PU development among Dutch nurses.⁽¹²⁾

Study 1: The Dutch Pressure Ulcer Prevalence Survey of 2003

Each year from 1998 on, a national prevalence registration of PU is held among Dutch health care institutions. This registration is set up in a way that accurate and reliable data on the scope and the severity of PU with a uniform instrument in different health care settings can be collected.⁽¹¹⁾ Within each institution, the policy to reduce the PU prevalence rate relies on the following 11 quality-indicators⁽¹¹⁾:

- 1) the existence of a PU committee; 2) the availability of a written protocol for the prevention of PU; 3) the availability of a written protocol for the treatment of PU; 4) the presence of a responsible nurse who keeps the protocols for prevention and/or treatment of PU up to date, and brings them under the attention of the employees; 5) the presence of a person who checks whether guidelines and/or protocols are followed or implemented; 6) the central registration of patients prone to PU, as well as; 7) of patients with PU; 8) management of PU prevention material at the institutional level, as well as; 9) on ward level; 10) the possibility to follow extra training sessions and refresher courses regarding PU prevention and treatment (for the past two years), and 11) the availability of an information brochure for patients and/or family members regarding PU prevention.

For the present study, prevalence rates were calculated at the institutional level. To standardize the patient populations, the rates were calculated only for those patients at high risk for developing PU. This risk is measured by the Braden-scale, a tool for evaluating PU risk, conform a score less or equal to 20.⁽¹⁴⁾ The Braden-score is a sum score of 6 subscales; sensory perception, activity, mobility, moisture, nutrition, friction and shear. Only the PU developed in the own institution was taken into account in calculating prevalence rates.

Study 2: The 2003 cross-sectional study among nurses in the Netherlands

This study was designed to investigate the knowledge of, the beliefs in, and the use of preventive methods, applied for the PU problem. The survey sample consisted of nurses ($N = 345$) who were randomly approached through their affiliation to an institution participating in the 2003-Dutch National Pressure Ulcer Prevalence Survey. Questions were formulated about the knowledge of, and beliefs in preventive methods and the actual use of these methods in practice. For the present study, we focussed on the questions regarding knowledge and actual use of massage as a preventive method for PU.

Regarding the question about knowledge and usefulness of massage in the prevention of PU, response categories were respectively 'always', 'sometimes', 'never' and 'I don't know'. The categories 'always', 'sometimes', 'never' were used for the question about the actual use of massage in practice. Based on the Dutch national guideline of 2002 the knowledge and practice were judged as right or wrong.⁽⁷⁾ The nurses' knowledge regarding the use of massage, and the actual practice of it did not correspond with the prescribed 2002 CBO-guidelines. It is plausible that this gap between theory and practice is partly caused by the 'quality' of the Dutch national guidelines, which are not all evidence-based.⁽¹³⁾

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Data-analysis

For the combination of results of the Dutch PU prevalence survey (study 1) and of the cross-sectional study of 2003 (study 2), we only considered the data from general hospitals. First, frequencies regarding the quality indicators, knowledge and practice, and the mean prevalence scores were calculated. Next, possible relations were investigated by using Pearson correlation coefficients (Pearson r). For this analysis the data from study 1 and study 2 were aggregated to the hospital level and then combined in one data-file. By applying aggregation, mean values of the included variables were used. From study 1, the presence-percentages of the 11 quality indicators, the institutional prevalence rates of PU and the Braden-scores of the observed patients at high risk for PU ($BS \leq 20$) were aggregated at the institutional

level. From study 2, the answers on the questions regarding knowledge and practice of massage as a preventive method for PU were aggregated at the institutional level.

4 | Results

Study 1: The Dutch Pressure Ulcer Prevalence Survey of 2003

In total, 43 general hospitals participated, in which 7,956 patients were scored on the presence of PU. The overall prevalence rate for these hospitals was relatively high, i.e. 22.2%. For the present study, we only concentrated upon 20 of these 43 hospitals, because they also participated in the cross-sectional study of 2003. The overall PU prevalence rate in these hospitals (4,335 patients) was 20.4%.

Table 1 shows that in these hospitals the 11 quality indicators were present in percentages ranged between 55% to 95%. The least represented indicators were 'the presence of a person who checks whether guidelines and/or protocols are followed or implemented (testing) (60%)' and 'management of PU prevention material on ward level (55%)'.

	Presence (%)
PU committee	90 (18 hospitals)
Prevention protocol	90 (18 hospitals)
Treatment protocol	95 (19 hospitals)
Responsible nurse	95 (19 hospitals)
Follow-up implementation guidelines	60 (12 hospitals)
Registration of patients prone to PU	80 (16 hospitals)
Registration of patients having PU	80 (16 hospitals)
Management on institutional level	95 (19 hospitals)
Management on ward level	55 (11 hospitals)
Training possibilities / refresher courses	90 (18 hospitals)
Information brochure	80 (16 hospitals)

Table 1 | The presence of quality indicators determining PU-policy, in percentages (N=20 general hospitals).

Study 2: The 2003 cross-sectional study among nurses in the Netherlands

Table 2 shows the accordance between the answers regarding knowledge and practice, as given by 342 nurses (3 missings). For instance, when looking in the knowledge category 'never useful', in total 33.6% of the nurses thinks that massage is never effective as a preventive method for PU. Interestingly, a far higher percentage, i.e. 51.2%, claims to never use massage in practice (see practice category 'never'). Still 48.8% of the nurses says they practise massage sometimes or always for preventing PU.

This table also learns that 52.3% of the nurses gives the same answer on the knowledge and the practice question, which is not very high. Remarkably, some nurses (7.3%) indicated that massage is never useful but still use it sometimes.

		Knowledge				
		Always useful	Sometimes useful	Never useful	Don't know	Total
Practice	Always	7 (2.0%)	6 (1.8%)	0 (.0%)	0 (.0%)	13 (3.8%)
	Sometimes	43 (12.6%)	82 (24.0%)	25 (7.3%)	4 (1.2%)	154 (45.0%)
	Never	14 (4.1%)	57 (16.7%)	90 (26.3%)	14 (4.1%)	175 (51.2%)
	Total	64 (18.7%)	145 (42.4%)	115 (33.6%)	18 (5.3%)	342 (100.0%)

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Table 2 | Cross tabulation of knowledge and practice of 342 nurses regarding massage for preventing PU.

Results from the merged data-files of study 1 and study 2

Pearson correlation coefficients between the quality indicators on one hand and the answers given on the questions regarding respectively knowledge and practice of massage in preventing PU on the other hand are presented in Table 3. The knowledge and practice answers of the 345 nurses were aggregated on hospital level.

Quality Indicators of PU-policy	Knowledge about the use of massage for preventing PU		Practice of massage in preventing PU	
	Pearson r	Sig.	Pearson r	Sig.
PU committee	-.340	.143	-.255	.277
Prevention protocol	-.451*	.046	-.212	.370
Treatment protocol	-.432	.057	-.260	.268
Responsible nurse	-.432	.057	-.260	.268
Follow-up implementation guidelines	-.512*	.021	-.418	.067
Registration of patients prone to PU	-.325	.162	-.323	.164
Registration of patients having PU	-.233	.323	-.264	.260
Management on institutional level	-.432	.057	-.260	.268
Management on ward level	-.257	.273	-.035	.883
Training possibilities / refresher courses	-.260	.269	-.219	.353
Information brochure	-.275	.241	.007	.975

*correlation is significant at the 0.05 level (2-tailed)

Bonferonni correction $\alpha_E = 0.00227$

Table 3 | Pearson correlations between the quality indicators determining PU-policy and: 1) knowledge of the nurses regarding the use of massage as a preventive method for PU (left column); and 2) the use of massage in practice (right column) for PU-prevention (N=20 general hospitals).

This table shows that, at the institution level, only the presence of a prevention protocol and the regular follow-up of the guidelines implementation are significantly related to the knowledge nurses have about the usefulness of massage in preventing PU. There seems to be no significant relation

between quality indicators and the actually performed practice.

The Pearson r between the nurses' scores on performed practice and knowledge is smaller before aggregation ($r=.437$, $p<0.01$) than that after aggregation ($r=.599$, $p=0.01$). Due to the aggregation, these differences may occur. That there exists a positive correlated relation between knowledge and practice was in accordance with the expectations.

We also calculated the Pearson correlations between the institutional prevalence rates (P) and their quality indicator scores on one hand and the scores on 'knowledge' and 'practice' on the other hand (Table 4a + 4b).

	Overall prevalence rate of the 2,171 high-risk patients	
	Pearson r	Sig.
PU committee	-.696**	.001
Prevention protocol	-.308	.186
Treatment protocol	-.432	.057
Responsible nurse	-.432	.057
Follow-up implementation guidelines	-.386	.093
Registration of patients prone to PU	-.120	.614
Registration of patients having PU	-.537*	.015
Management on institutional level	-.432	.057
Management on ward level	-.394	.086
Training possibilities / refresher courses	-.336	.148
Information brochure	-.335	.149

*correlation is significant at the 0.05 level (2-tailed)

**correlation is significant at the 0.01 level (2-tailed).

Bonferonni correction $\alpha_E = 0.00454$

Table 4a | Pearson correlations between the quality indicators determining PU-policy, and the institutional overall prevalence rate ($N=20$).

As the data show, both the presence of a PU committee within the institution and the regular registration of patients that develop PU are related to the registered prevalence rate. As shown in Table 4b, the nurses' knowledge and practice regarding the use of massage for preventing PU were not significantly related to the registered prevalence rate.

	Overall prevalence rate of the 2,171 high-risk patients	
	Pearson r	Sig.
Knowledge	.227	.337
Practice	.062	.794

Table 4b | Pearson correlations between nurses' knowledge and practice, and the institutional overall prevalence rate.

5 | Discussion

This study shows that within 20 general Dutch hospitals in which a thorough survey of knowledge and practice of massage in the prevention of pressure ulcer development was organized, no significant relation could be established between the knowledge and practice of nurses regarding their knowledge and practice of massage and the prevalence rates of pressure ulcers. According to our results, only the nurses' knowledge and their practice are positively correlated, before and after aggregation. Regarding the institutional policy on the prevention and development of pressure ulcers, we found that only 2 out of 11 quality-indicators showed a positive correlation with to the pressure ulcer prevalence rate. Another 2 indicators positively correlated with the existing knowledge of nurses regarding the use of massage in pressure ulcer prevention.

Before answering the formulated research questions in more detail, it should be emphasized that the presence of quality indicators among the investigated hospitals only ranged between minor limits (Table 2). This probably affected the calculated correlation coefficients. Furthermore, it is

important to be aware of the ecological fallacy. These results indicate the stand of affairs regarding the relations between PU-policy, knowledge, practice and prevalence rates for patients of Dutch general hospitals at high risk for PU. Due to the use of Pearson's r no causal conclusions can be drawn. Through the used selection-process of the nurses participating in the 2003-cross-sectional study, selection-bias can possibly influence results and hamper generalisation. They were all employed in an institution participating at the annual prevalence survey.

The large differences between the percentages of knowledge and practice in the always- and never category (Table 2) confirm the existing discrepancy between theory and practice as mentioned before. The difference can also partly be explained by the increased workload over the years and/or the tendency to give social-desirable answers.

That nurses' knowledge and practice correlate positively is in accordance with our expectations. However, as a Pearson r of .60 it is not a very high, the association between nurses' beliefs and practices can not be considered to be very strong. This was already visible in Table 1. Other factors, besides knowledge, are apparently of influence on nurses' practice. As mentioned earlier, workload, for instance, can influence actual performances on the work floor.

Furthermore, knowledge and practice do not seem to be related to the registered prevalence rates. In other words, it does not seem to matter if massage is applied in practice or not. This confirms the findings of the study based on the previous randomized controlled trial by Duimel *et al.*⁽¹⁶⁾

The presence of a pressure ulcer policy within an institution seems to be related to registered knowledge of the nurses and institutional prevalence rates. The presence of a pressure ulcer committee is positively correlated with the registered prevalence rates, but we must keep in mind that almost all hospitals had such a committee. Therefore, no definite conclusions regarding causality can be drawn. It seems plausible to argue that the presence of a PU committee may affect nurses' knowledge, but this knowledge may inversely also promote the introduction of a pressure ulcer committee and/or its actions taken.

In our study, neither knowledge nor practice showed a relation with the

pressure ulcer prevalence rates. Also a sound relation between knowledge and practice did not seem to influence the prevalence rates. This seems to indicate that the opinion of nurses about the usefulness of massage in the prevention of pressure ulcers and the application of it in practice is without any consequence for the prevalence of pressure ulcers.

6 | Conclusion

In this study, we focussed on massage; a non-effective preventive method for pressure ulcers, which is still used in practice although (inter)national guidelines advice against its use. To find out whether knowledge and use of massage could influence the institutional pressure ulcer prevalence rates, this study was performed. It was investigated whether the institutional pressure ulcer policy was also related to prevalence rates and which factors were more related: the individual or the institutional factors.

It can be concluded that neither knowledge nor practice is related to the pressure ulcer prevalence rates, and that only 2 out of the 11 quality-indicators showed a slightly positive relation with the prevalence rate. As expected, there was a sound relation between nurses' knowledge and their performed practice. However, whether their opinion was to belief in the usefulness of massage or not or whether they perform massage or not, no confirmed indications exist that any argument whatsoever influences the prevalence rates. Therefore, it seems more important to emphasize on evidence-based issues regarding pressure ulcer prevention, such as the prevention of pressure and shear forces and regular change of position. Therefore, we recommend to pay more attention to methods described as useful in (inter)national guidelines during the implementation-process.

7 | Acknowledgements

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8 | References

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Chapter 6

The effectiveness of massage with and without Dimethyl Sulfoxide in preventing pressure ulcers: A randomized, double blind cross-over trial in patients prone to pressure ulcers

Inge GP Duimel-Peeters, Halfens RJG, Anton W Ambergen,
Ronald H Houwing, Martijn PF Berger, Luc HEH Snoeckx

Introduction: Pressure ulcers (PU) are a great problem in Dutch health care institutions. Several preventive methods are used in practice to prevent PU development. One of them is massage, although massage is dissuaded (according to national and international guidelines) because it could be harmful to underlying tissues. Nevertheless, a survey held in Dutch hospitals showed that almost all nurses evaluated massage as an effective method. Two other cross-sectional studies stated also that what is used in practice does not necessarily correspond to what is theoretically recommended. **Aim:** We wanted to evaluate the use of massage as a preventive method for PU and did compare this intervention with a group getting only change of position as a preventive method for PU. **Research Question:** Does massage with an indifferent cream, and with a DMSO-cream combined with a 30° change of position, administered each 6 hours, lead to a lower incidence of pressure ulcers compared with getting only change of position? **Method:** Eight nursing homes participated at the R.C.T.. Only high-risk patients who comply with the inclusion criteria were included. Two of the three interventions were randomly assigned at each ward. Each intervention took 4 weeks. Between the two interventions, there was a wash-out period of 2 weeks. Pressure ulcers will be measured according to the four grading system of the EPUAP. The duration of the massage was standardized by the fingertip unit, as described by Long. **Results:** The interventions 'only change of position', 'massage with an indifferent cream' and 'massage with a DMSO-cream', do not differ significantly. DMSO did not fulfil the expectations based on a literature- and a former done pilot-study.

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In addition to being painful for patients, pressure ulcers (PU) are a major and costly problem in various health care institutions in the Netherlands.⁽¹⁻³⁾ Several methods are used in practice to prevent pressure ulcer development. One of these methods is massage. Although massage is internationally no longer officially recommended as a preventive method, the technique is still practiced in health care.⁽⁴⁻⁵⁾ Massage is discouraged because it is thought to cause injuries to the skin. Nevertheless, a recent evaluation study reported that nearly all hospital nurses regarded massage as a very effective method for the prevention of pressure ulcers, which is a reason for them to continue this intervention.⁽⁷⁾ The same conclusion was drawn from interviews with healthcare workers in nursing homes.^(8,9)

Quantitative research into the effects of massage has been scarce and limited.⁽¹⁰⁾ In an extensive survey, our research group recently found that the number of studies on this topic was very limited and that the existing studies were of minor methodological quality.⁽¹¹⁾ Therefore, further research on the effectiveness of massage, using statistically proven, quantitative data is clearly needed.

A confounding factor in studies on massage is the influence of concomitant position changes during the massage treatment. For instance, Defloor⁽¹²⁾ found that changing patients' position every two hours resulted in a 14.3% incidence of pressure ulcer injuries, whereas changing positions every three hours led to significantly more pressure ulcers, viz., in 24.1% of the patients. A combination of changing patients' position every 6 hours and having them lie on a poly-urethane mattress reduced the incidence rate to 15.9%. In the control group, which received the usual preventive methods applied at the institution (not including position changes), 20% of the patients developed pressure ulcer injuries. Although most official guidelines recommend regularly changing patients' position (every 2 - 4 hours), it is known that this does not happen as regularly as necessary.^(13,14)

The interest in the problem of pressure ulcers is obvious from the increasing application of new insights into the pathophysiological basis of the development of pressure ulcers. For instance, studies with laboratory animals have

demonstrated that pressure ulcers develop as a result of recurrent ischemia-reperfusion events, in which toxic oxygen-derived free radicals are produced.⁽¹⁵⁾ An argument supporting this hypothesis is provided by the finding that oral administration of antioxidants can be effective in preventing the occurrence of pressure ulcers.⁽¹⁶⁻²⁰⁾ Instead of oral administration locally administered antioxidants could have the same beneficial effects. Dimethyl sulfoxide (DMSO) is a potent scavenger of radicals – especially of the very toxic hydroxyl radical - which penetrates the skin very well. In concentrations below 50% the product is not toxic.⁽²¹⁾ A pilot-study in patients at high risk of pressure ulcers showed that massaging with a DMSO-containing cream leads to a decrease in pressure ulcer occurrence among these patients.⁽²²⁾

The present study intended to assess the effects of massage, including scavenging of oxygen-free radicals, and position changes. Interventions consisting of 'massaging with an indifferent cream combined with position changes' were compared with 'massaging with a DMSO-cream combined with position changes' and with 'only position changes' only.

The following research questions were therefore formulated: (1) Does massaging with an indifferent cream combined with 30° position changes administered at 6-hour intervals to a group of pressure ulcer-prone patients lead to a lower incidence of pressure ulcers compared to a group getting only 30° position changes' administered in a time-interval of 6 hours?; (2) Does massaging with a 'DMSO-cream' combined with 30° position changes' administered at 6-hours intervals to a group of pressure ulcer-prone patients lead to a lower incidence of pressure ulcers compared to a group getting only 30° position changes' administered in a time-interval of 6 hours?; (3) Does massaging with a 'DMSO-cream' combined with 30° position changes' administered at 6-hours intervals to a group of pressure ulcer-prone patients lead to a lower incidence of pressure ulcers compared to massaging with an indifferent cream combined with 30° position changes' administered in a time-interval of 6 hours?

Design

The study was designed as a randomized, double-blind cross-over trial, in which patients of eight Dutch nursing homes who complied with the inclusion-criteria consecutively received two of the three interventions with a two-week wash-out period. The nursing homes were comparable in terms of guided pressure ulcer policy. Only patients in nursing homes were asked to participate because they have the highest prevalence rates of pressure ulcers in the Netherlands and the population is rather stable over a long time.^(23,24) Two treatment periods of four weeks each were used because a four-week observation period has frequently been recommended in pressure ulcer research.⁽²⁵⁻²⁷⁾

Patients

Inclusion-criteria were the following: (1) the intervention had to mean no drawback to the patient, (2) the patient had to have a light skin colour, (3) the patient had to reside at a long-stay ward of a nursing home for more than two months, (4) the patient had to rest on an anti-pressure ulcer mattress (i.e. poly-urethane mattress or equivalent), (5) the patient or his/her legally representative had to be willing and able to sign the informed consent form; and (6) the patient had to be at high risk of developing pressure ulcers according to the Braden scale using a cut-off point of 20.

Exclusion-criteria were: (1) the patient was already being treated with massage for another medical indication (and it was not possible to end this treatment), (2) the patient was to undergo surgery in the nearby future or had undergone surgery less than two weeks ago, (3) pressure ulcers were already present at the coccyx, heels or ankles (the only places that were massaged in this research), (4) the patient was expected to have short length of stay or (5) a short life expectancy (< 10 months).

Interventions

In order to prevent information bias due to errors in performing the assigned intervention from one patient to another, and to decrease the work-

load and time to be invested by the executive healthcare workers, only two of the three interventions were randomly assigned to each ward (by throwing up dice), and not at patient-level.

The three interventions were:

1. A 2- to 3-minute massage of the coccyx, both heels and ankles with an indifferent cream, combined with a 30° position change. This procedure was repeated every 6 hours for 4 weeks (Treatment A).
2. A 2- to 3-minute massage of the coccyx, both heels and ankles with a 'DMSO-cream' (see below), combined with a 30° position change. This procedure was repeated every 6 hours for 4 weeks (Treatment B).
3. Only 30° position change, repeated every 6 hours for 4 weeks (Treatment C).

The decision to change patients' position every 6 hours and the precondition of anti-PU mattresses being used were based on the resulting reduced workload for the executive healthcare workers. For ethical reasons we did not include a control group of patients not receiving any treatment. Because national guidelines encourage regular position changes, it would not be appropriate to do the opposite of what is nationally recommended. Therefore, we regarded group C as the control group of our study.

To prevent possible carry-over effects, the first four-week treatment period was followed by a two-week wash-out period before the next intervention was started. Cremor vaselini cetomacrogolis FNA was used as the indifferent cream. This version of Vaseline is spread more easily and protects the skin of elderly people against dehydration. The DMSO-cream consisted of the same cream with an additional 5% dimethyl sulfoxide added. Patients were massaged at the coccyx, the heels and the ankles as Bours *et al.* have reported that these three skin areas are responsible for the highest prevalence rates in Dutch health care institutions.^(23,28-29) To decrease the workload of the participating healthcare workers, other areas at risk such as elbows, hipbones, and knees were not included. Massage was performed while wearing a hand glove, making soft circular movements. The duration of the massage was standardized, as was the amount of cream to be used. The amount was standardized using the fingertip unit (FTU), as described by Long.⁽³⁰⁾ One FTU

is the amount of cream spread over the length of the last metatarsal of the forefinger, i.e. about 0.5g and 0.45g for men and women, respectively. This covers 300 and 250 cm² of skin, respectively. Before the start of the trial, one patient was massaged by the same nurse with the indifferent cream for 1 week, exactly as it was to be done during the experimental period. At the beginning and end of this week, the amount of cream used was weighed and was compared with Long's findings.⁽³⁰⁾ The amounts of cream used for the various body parts were 2 FTUs for the coccyx, 1 FTU for the heel, and 0.5 FTU for each ankle (medialis and lateralis).

One week before the start of the trial, each participating ward was informed about the theoretical background of the study, the work to be expected and the correct way to perform the interventions. The 30° position change can be performed by a single nurse using pillows (semi-fowler position). This instruction was orally and visually explained to the nurses.⁽³¹⁾

Instruments

The *Braden scale* is one of the best-known and most widely used tools for evaluating pressure ulcer risk with proven validity and reliability for risk assessment.^(29,32) The scale consists of 6 subscales reflecting determinants of pressure (sensory perception, activity, and mobility) and factors influencing tissue tolerance (moisture, nutrition, and friction and shear).⁽³³⁾ Possible scores range from 6 to 23. This scale was used as an inclusion criterion (a score ≤ 20 meaning the person is at risk of pressure ulcers). Halfens et al.⁽³²⁾ used a cut-off point of 20 and reported a sensitivity of 73% and a specificity of 70%.

The presence of pressure ulcers was evaluated with the help of the *four-grade system* of the European Pressure Ulcer Advisory Panel (Table 1) using a transparent disk.⁽³⁴⁻³⁵⁾ Because of the reversibility of grade I ulcers, these ulcers were only recorded as pressure ulcers if they were still present after 4 hours and if two external observers confirmed the nurses' conclusion of grade I. When pressure ulcers did occur, the body location, but not the patient was excluded from the research.

Table 1 | Grading System of Pressure Ulcers⁽³⁵⁾

Grade Description

- I Non-blanchable discoloration of intact skin;
- II Partial-thickness skin loss involving epidermis, and/or blister or shallow ulcer without undermining of adjacent tissue;
- III Full-thickness skin loss involving damage or necrosis of the epidermis and/or dermis not extending to underlying bone, tendon or joint;
- IV Full-thickness skin loss involving damage or necrosis of the epidermis and/or dermis extending to underlying bone, tendon or joint.

A transparent disk⁽³⁴⁾ with a diameter of 6.5 cm was used to assess local redness. This involved first releasing the pressure on the body part, for example by changing the patients' position. If the local redness persisted after 10 minutes, when pushing the convex lens against the skin, the grade 1 pressure ulcer was confirmed.

The presence of pressure ulcers and their grade according to the system shown in Table 1 were used as an outcome measurement.

Distribution of the patient sample

Two treatment periods of four weeks each were distinguished, separated by a two-week wash-out period. Table 2 shows the frequencies of the distribution of the population for the two periods.

Table 2 | Frequency table for the two treatment periods.

	Period 1	Period 2	Total
Massaging with the indifferent cream (Treatment A)	32 (40.5%)	27 (34.2%)	59
Massaging with the DMSO-cream (Treatment B)	29 (36.7%)	26 (32.9%)	55
Only position change (Treatment C)	18 (22.8%)	21 (26.6%)	39
Total	79 (100%)	74 (93.7%)	
Missing		5 (6.3%)	

In total, 59 patients received massage with the indifferent cream, 55 patients were massaged with the DMSO-cream and 39 patients underwent only position changes.

Treatments were administered in six different orders (Table 3). Each ward was assigned at random to one of these treatment orders, so that each ward used a different treatment scheme during the second period than during the first period.

Table 3 | Distribution of the patients over the various treatment orders.

Period 1	Period 2	Total Patients
Treatment A	Treatment B	20
Treatment B	Treatment C	12
Treatment A	Treatment C	9
Treatment B	Treatment A	16
Treatment C	Treatment B	6
Treatment C	Treatment A	11
		Sub-total: 74
Treatment C	Not participated in treatment B	1
Treatment A	Not participated in treatment C	3
Treatment B	Not participated in treatment A	1
		Missing: 5

Data processing

The healthcare workers who applied the treatments at the participating institutions signed the patients' personal journal after each treatment. When pressure ulcers were identified, they were classified by recording the grade and date of confirmation in the same journal. Every two days, the trial leader and an independent registered nurse visited the wards, consulted the journals and the healthcare worker responsible for the treatment, and verified the existence of pressure ulcers for each individual patient.

Analysis

Differences in characteristics between patients in the various treatment groups were tested for each period with Chi-square tests for categorical

data and *t* tests for continuous data. Mann-Whitney and Kruskal-Wallis tests were used because of non-normality of some variables. In order to obtain a preliminary overview of the influence of the three treatments on the outcome variable, frequency tables were constructed for each treatment period. Furthermore, because of the dichotomous outcome variable (PU development or no PU development), logistic regression was used to examine the results of each treatment in terms of pressure ulcer prevention.

Logistic regression was performed within each period. Dummy variables were introduced for the treatment received in each period, in such a way that treatment C was always coded as the control group. To correct for possible confounding variables, we added several covariates (together and separately) that are assumed to be correlated with PU: length, weight, body mass index (BMI), length of stay on the ward (in months), age, sex, incontinence level, type of pressure-relieving cushions used and use of other preventive methods. Non-significant covariates were removed using backward deletion. Finally, Kaplan-Meier curves were constructed to obtain a clearer representation of the survival prognosis for each treatment.

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3 | Results

Sample

A total of 79 patients, residents of eight Dutch nursing homes, were eligible for the study. Fifty-five patients (69.6%) were female. The mean age was 81.3 (SD = 9.76), with a range of 45 to 97. There were no significant differences in patient characteristics for the different comparisons. The characteristics of the patients are shown in Table 4, which presents separate values for each treatment period.

Characteristics	Period 1	Period 2	Characteristics	Period 1	Period 2
Age			Incontinence		
Mean	81.43	81.62	Not incontinent	5.1%	4.1%
SD	9.76	9.60	Totally incontinent	57.0%	59.5%
Median	83	82.50	Sometimes incontinent	29.1%	27.0%
Range	45-97	45-97	Only incontinent for urine	7.5%	8.1%
			Missing	1.3%	1.3%
Gender					
Female	55=69.6%	52=70.3%			
Length (in cm)			Type of cushion in seat/wheelchair		
Mean	166.50	166.58	No cushion	48.1%	48.6%
SD	8.71	8.63	Gel cushion	3.8%	4.1%
Median	168	168	Air cushion	13.9%	14.9%
Range	140-180	140-180	Blister cushion	2.5%	2.7%
Weight (in kg)			Foam cushion	20.3%	18.9%
Mean	61.18	60.83	Vessel cushion	3.8%	4.1%
SD	14.41	14.63	Other	6.3%	5.4%
Median	61.25	61	Missing	1.3%	1.3%
Range	25-95	25-95			
Body Mass Index			Other preventions		
Mean	21.80	21.60	No other prevention	72.2%	71.6%
SD	4.91	4.85	Heel protection	7.6%	8.1%
Median	21.15	20.90	Soft pillow under the coccyx	2.5%	2.7%
Range	11-35	11-35	Catheter	6.3%	6.8%
			Resting with heels free	5.1%	5.4%
Length of stay on the wards (in months)			Other or combinations	5.1%	4.1%
Mean	47.90	47.51	Missing	1.2%	1.3%
SD	31.41	30.60			
Median	40	40			
Range	7-144	7-144			

Table 4 | Characteristics of the sample, including residents of 8 nursing homes (N=79)

The patient characteristics we assessed also included incontinence, as several earlier prospective observational studies of pressure ulcer incidence also included incontinence as a risk factor.⁽³⁶⁻⁴⁰⁾ In addition, knowing that a patient is incontinent should make the observer take extra care to distinguish between incontinence injuries and pressure ulcers.

Differences between periods

Table 5 shows the PU incidence rates, by grade, for the two treatment periods. In general, grade I accounted for 38.5% of the incidence rates for treatment period 1, and for 6.3% of the incidence rates for treatment period 2. Patients with pressure ulcers were rated as at high risk according to the Braden scale, and we used a cut-off point of 20.

	Grade I	Grade II	Grade III	Grade IV	Total	PU development by week
Treatment period 1	38.5%	10.3%	0%	0%	48.8%	Week 1: 24.4%
					(38/78)*	Week 2: 14.4%
						Week 3: 8.6%
						Week 4: 1.4%
Treatment period 2	6.3%	4.7%	0%	0%	11%	Week 1: 6.3%
					(7/64)**	Week 2: 3.1%
						Week 3: 0%
						Week 4: 1.6%

*1 missing score for PU-development

**10 missing scores for PU-development and/or grade recording

Table 5 | Incidence of PU by grade, by treatment period and by week, in percentages.

Thirty-eight patients (48.8%) developed pressure ulcers in treatment period 1. Most of the pressure ulcers developed in week 1 of both periods. Of those 19 patients (24.4%) who developed PU in week 1 of treatment period 1,

3 were receiving treatment A, 15 were receiving treatment B, and 1 was receiving treatment C. In treatment period 2, 7 (11%) patients developed pressure ulcers. Of the 4 (6.3%) patients who developed PU in week 1, 1 was receiving treatment A, 2 were receiving treatment B and 1 was receiving treatment C.

In both periods, most pressure ulcers developed at the coccyx (17.7% and 6.3%, respectively). The combination of 'coccyx and heel' PU also occurred frequently (10.1%) in treatment period 1, followed by PU at the heel only (i.e. 8.9%). Pressure ulcers at the 'ankle', and combinations of 'coccyx and ankle' or 'heel and ankle' were not common in period 1 (2.5% for each of the three). In period 2, PU at the 'heel' and combinations of 'heel and ankle' occurred in 1.3% of the patients. Most patients developed their PU in week 1 of both periods, with a strong decreasing tendency for every following week.

Differences between treatments

The frequency of PU in each period is presented in Tables 6 and 7. In both periods, Chi-square-tests were not significant, resulting in p -values of 0.189 and 0.726. However, there was an obvious difference between the periods in the occurrence of pressure ulcers. During the first period, the effect of massaging with the indifferent cream was almost the opposite of massaging with DMSO-cream (Table 6), whereas during the second period, it seemed not to matter which treatment was used to prevent pressure ulcers (Table 7).

	No Pressure Ulcers	Pressure Ulcers	Total
Only position change	11 (61.1%)	7 (38.9%)	18 (100%)
Massaging with the indifferent cream	18 (58.1%)	13 (41.9%)	31 (100%)
Massaging with the DMSO-cream	11 (37.9%)	18 (62.1%)	29 (100%)
Total	40 (51.3%)	38 (48.7%)	78* (100%)

Chi-square = 3.336; $p = 0.189$

*1 missing value for the variable 'development of PU-scores'

Table 6 | Frequency table for treatment period 1 and development of pressure ulcers.

	No Pressure Ulcers	Pressure Ulcers	Total
Only position change	16 (94.1%)	1 (5.9%)	17 (100%)
Massaging with the indifferent cream	19 (86.4%)	3 (13.6%)	22 (100%)
Massaging with the DMSO-cream	22 (88.0%)	3 (12.0%)	25 (100%)
Total	57 (89.1%)	7 (10.9%)	64* (100%)

Chi-square= .639 (3 cells have expected count less than 5); $p = 0.726$

*5 missing values for people not participating in treatment period 2, and another 10 missing values for the variable 'development of PU-scores'

Table 7 | Frequency table for treatment period 2 and development of pressure ulcers.

It can be concluded that the addition of DMSO to the indifferent cream had no effect on the occurrence of pressure ulcers.

Logistic Regression

Separate logistic regressions were performed for the two treatment periods. For the received treatment separately, dummy variables were included whereby the change of position group without massage was coded as the control group.

Treatment period 1

There was no treatment effect in period 1. The p -value for the group massaged with the indifferent cream was .834 (OR=1.135), while that for the DMSO-group was .126 (OR=2.571) (see Table 8).

	B	S.E.	Wald	Df	p-value	OR
Massaging with an indifferent cream (Treatment A)	.127	.605	.044	1	.834	1.135
Massaging with DMSO-cream (Treatment B)	.944	.617	2.346	1	.126	2.571
Constant	-.452	.483	.874	1	.350	.636

Table 8 | Final model of the logistic regression for treatment period 1.

The final model resulted in the following equation:

$$\text{Ln(odds)} = -0.452 + 0.127 \times \text{Treatment A} + 0.944 \times \text{Treatment B}$$

The covariates did not significantly affect the Ln(odds) of pressure ulcers.

Treatment period 2

In the second period, we found *p*-values of .441 (OR=2.526) and .516 (OR=2.182) for treatment A and treatment B respectively (see Table 9).

There were more missing values in this period than in the first period.

	B	S.E.	Wald	Df	<i>p</i> -value	OR
Massaging with an indifferent cream (Treatment A)	.927	1.204	.593	1	.441	2.526
Massaging with DMSO-cream (Treatment B)	.780	1.201	.422	1	.516	2.182
Constant	-2.773	1.031	7.235	1	.007	.063

Table 9 | Final model of the logistic regression for treatment period 2.

The final model for treatment period 2 was:

$$\text{Ln(odds)} = -2.773 + 0.927 \times \text{Treatment A} + 0.780 \times \text{Treatment B}$$

Kaplan-Meier survival curves

Survival analysis can be regarded as a logistic regression analysis including more additional information, meaning that whereas logistic regression analysis uses cumulative incidence rates, survival analysis uses incidence densities.

Two plots of Kaplan-Meier survival curves for pressure ulcer occurrences are shown in Figures 1 and 2 for each of the two treatment periods.

Figure 1 | KM-curve for treatment period 1

Figure 1 shows that massaging with the indifferent cream (treatment A) or only changing of positions (treatment C) seemed to result in better pressure ulcer-free prognosis than being massaged with the DMSO-cream (treatment B). As times goes on, the dashed and bold curves appear to grow further apart (until day 18), suggesting that the beneficial effects of only changing position relative to massaging with a DMSO-cream increase as treatment continued for a longer period. However, beyond day 18, the three treatments tended to have the same effects.

Figure 2 | KM-curve for treatment period 2

Figure 2 shows that there are minimal step functions because of the relatively small N and the missing values in treatment period 2. But even here, massaging with the indifferent cream (treatment A) is preferable to the use of DMSO-cream.

4 | Discussion

Pressure ulcers are still a major problem, as is confirmed by our high incidence rates. This study was intended to contribute to the establishment of adequate pressure ulcer prevention by investigating the effects of massage as a preventive method.

We did not find any significant differences between the three treatments and found no evidence of any positive influence of massaging with a DMSO-containing cream. Although there were no significant results, we tentatively conclude that position changes alone are to be preferred to massaging the skin areas that are most at risk in high-risk patients. If massage is pre-

ferred, a simple indifferent cream will suffice. In spite of the hopeful results of an earlier pilot study⁽²²⁾, our study did not confirm that the use of DMSO leads to a marked decrease in pressure ulcer development among high-risk patients. We even presume that using a larger study population, which would enlarge the 'negative' effect of the DMSO-cream, could result in (marginally) significant effects. Most of the developed pressure ulcers that developed appeared in the first two weeks, suggesting that habituation after some time decreases the occurrence or development of pressure ulcers. The most common location where pressure ulcers developed was the coccyx, followed by heel and ankle. This outcome is consistent with the assumptions made about the anatomic locations at risk.⁽⁴¹⁻⁴³⁾

The design involved a sample of 79 patients, divided over two treatment periods and three interventions. We preferred two treatment periods rather than three to shorten the trial period and to reduce the workload of the participating nurses and caregivers.

An explanation for the differences between the two treatment periods is hard to find. One possibility is that the motivation of the participants and the accuracy with which the treatments were applied in treatment period 2 was not comparable with that in treatment period 1. There were also more missing values for this second treatment period because some patients and relatives decided to end their participation, and because some of the participating health care workers got tired of applying the treatment as accurately as possible. In addition, the relatively small sample size hampered our analyses. The distribution of the population for each group sometimes became too small when splitting up covariates into several dummy variables. In such cases, we would for instance decide to use 'preventive cushions', with response options 'yes/no', rather than splitting the response categories up into all the initial response options initially identified. Selecting on diagnosis or medication would make the amount of participants also smaller, so we thought pragmatically. By randomizing the wards, and so the patients, towards the treatments, we considered the different groups as homogeneous regarding their different features, such as diagnosis or used medications.

Based on our results, it appears that massage is not as harmless the literature or guidelines sometimes suggest.⁽¹⁰⁾ It is possible that the main effect of massage lies in the accompanying additional position change that occurs with every massage treatment. Since we used no 'real' control group, it must be kept in mind that this study assessed the possible added value of massage to prevent pressure ulcers, rather than the effect of massage on its own. One could also assume that the nurses' hand-contact with the patients and the extra attention this implies affected the patients' psychological well-being. However our study did not investigate this.

The findings of the present study have certain consequences for the daily practice of treating patients at risk of PU. In view of the results, it seems that neither massaging with a DMSO-cream nor massaging with an indifferent cream is to be preferred as a method to reduce the high incidence rates of PU. Indeed, the 48.8% incidence rate in treatment period 1 is still extremely high, even when we keep in mind that continuous registration easily leads to underestimation of the occurrence of pressure ulcers. Therefore, we recommend that nurses and health care workers follow the national guidelines recommending regular position changes to prevent the development of PU.

5 | Conclusion

The outcomes of three treatments, viz. 'position changes only', 'massaging with an indifferent cream' and 'massaging with a DMSO-cream' did not differ significantly. There is no reason to assume that massaging with an indifferent cream is harmful to underlying tissues when it is provided gently with small circular movements. However, it would be desirable to take some tissue biopsies before and after massage treatment of patients prone to PU, in order to confirm the conclusion that massage is not harmful to skin and underlying tissues. However, from a deontological perspective, it is questionable whether or not such approach can be justified.

On the other hand, since no benefits of massage were found either, it seems that only position changes, are an effective method to prevent pressure ulcers on condition that they are applied regularly (every 2-4 hours), as

indeed recommended in the Dutch national guidelines.^(5,14,44) DMSO did not fulfil the expectations raised by the literature and an earlier pilot-study. If massaging, combined with position changes, is preferred, the use of an indifferent cream can be advised but one should be aware of the fact that massaging has nothing to do with PU prevention. It would be interesting to repeat this study in a larger population sample and with every patient undergoing all three treatments to improve statistical analyses. For now, we conclude that regular position changes can be effective as a method to prevent pressure ulcers, and that massaging with an indifferent cream, when applied in the right way as described above, will do no harm nor produce benefits.

6 | Acknowledgements

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Chapter 7

| General Discussion |

1 | Introduction

Massage is often used to prevent the development of pressure ulcers. In this dissertation, the beliefs in, the knowledge of and the use of massage and its effectiveness in preventing pressure ulcers have been investigated. In this last chapter the main findings are briefly summarized, and some theoretical and methodological reflections are presented. Finally, implications for practice and recommendations for future research will be forwarded.

2 | Main Findings

This thesis shows that massage techniques are generally well defined and described in the literature. Only one of them, i.e. effleurage, fits for the treatment of pressure ulcers because this technique seems to be harmless for tissues underlying the skin (chapter 2). In the daily practice, opposite opinions exist regarding the effectiveness of massage for the prevention of pressure ulcer development. This is exemplified by the difference between the content of existing guidelines and the actually performed practice of nurses and other health care givers (chapters 4 and 5).

One of the main conclusions of this thesis is that massage (as effleurage) does not prevent the development of pressure ulcers (chapter 6). On the other hand, massage (i.e. effleurage) does not have the expected negative effects on the human skin and pressure ulcer development as assumed by some authors.⁽¹⁻³⁾ Aside from that, in contrast with what is generally believed on the effectiveness of dimethyl sulfoxide (DMSO)^(4,5), this compound did not have the expected beneficial effects in patients prone to pressure ulcers (chapter 6). Our randomized clinical trial revealed that the outcome of patients treated with regular change of position on an anti-pressure ulcer mattress was not worse or better than that of patients that were treated with massage on the body parts prone to pressure ulcer development. Thus, to reduce cost and time investment in the daily care of nursing homes, it is preferable to treat patients prone to pressure ulcers with regular changes of positions without additional massage. As such, our findings support the Dutch national guidelines for the prevention of pressure ulcers.⁽⁶⁾

Relevance of the study

The relevance of this thesis lies in clarifying the existing discrepancy between theory and practice regarding the use of massage as a preventive method for pressure ulcers in the Netherlands. Our detailed analysis of literature studies was inspired by the observation that massage is still widely practised to prevent the development of pressure ulcers, even when the guidelines of the European Pressure Ulcer Advisory Panel and other (inter)national guidelines no longer recommend massage as a preventive treatment for pressure ulcers.⁽⁷⁻¹¹⁾ In fact, massage is dissuaded because it is considered to cause injuries of the skin. Nevertheless, research shows that almost all Dutch hospital nurses evaluated the use of massage as a very effective method.⁽¹²⁻¹⁴⁾ Objective reports of the possible beneficial effects of massage as a preventive method for pressure ulcers are scarce. The reported results in those studies are often not statistically significant while the overall methodological quality is questionable.^(15, 16) To facilitate the implementation of a (part of a) guideline it is important that it is based on sound evidence. Until now, only 5 percent of the current Dutch guidelines are evidence-based.⁽¹⁷⁾ Our epidemiological research was initiated to improve the understanding of the effects of massage, all or not in combination with DMSO, on pressure ulcer development.

Theories regarding the development of pressure ulcers

As described in chapter 1, two theories regarding the development of pressure ulcers have been postulated, i.e. the top-down and the bottom-up theory. The present thesis does not provide conclusive evidence to accept or reject one of the prevailing hypotheses regarding the development of pressure ulcers. Elucidating the aetiology of pressure ulcers is still an important domain for research. Until now, both theories are supported by scientific evidence. Irrespective of which theory is most acceptable, we are convinced that the scoring of the presence of pressure ulcers, as presented in chapter 6, was well performed. Indeed, if pressure ulcers are initiated in the epidermis - as the top-down hypothesis claims - our measurement of irreversible redness

of the skin seemed to be appropriate. On the other hand, when pressure ulcers first arise in the deep muscle layers covering bony prominences, as hypothesized in the bottom-up theory, it could be argued that these ulcers do not develop fast enough towards the skin surface, i.e. within 4 weeks, so that pressure ulcers can not be measured adequately through palpation and observation of the skin surface. Because it has been shown that ulcers, arising in the deep muscle layers and covering bony prominences, develop at a faster rate than superficial ulcers and yield more extensive ulceration, we assume that in this case the measurement of pressure ulcers through visible observation and palpation will also be satisfactory.⁽¹⁸⁾ It can not be excluded however, in case ulcers would have developed in deep layers in a late phase of the investigation, that we scored some patients as false negative.

4 | Methodological Reflections and Results

4.1 | Regarding the performed randomized controlled trial (chapter 6)

Design

For the study as presented in chapter 6, a randomized controlled trial (R.C.T.) conducted as a double-blind cross-over design was applied. In this design three different interventions were defined and randomized. To prevent information-bias, arising from errors in performing the assigned intervention from one patient to another, and to decrease the workload in time for the executive nurses and health care givers, only two of the three interventions were randomly assigned at each ward, and not at patient-level. The patients received these two interventions in a consecutive way with a wash-out period of two weeks between the two interventions.

It is clear that a complete statistical analysis could only have been performed if all patients were subjected to all three interventions. In that case however, we suspected that most nursing homes would not lend their cooperation because of the relatively high workload and time-investment. To avoid this situation, we anticipated with an adapted design.

The choice for changing the patients' position each 6 hours, instead of the more commonly prescribed 2-3 hours, was based on information from

Defloor.⁽¹⁹⁾ In this study it was found that the incidence rate of pressure ulcers was lower when the patients' position was changed each 6 hours in combination with a poly-urethane mattress (15.9%) then when the position was changed each 3 hours (24.1%). Another advantage of a change of position each 6 hours was the decreased workload for the nurses.

Inclusion criteria

For our patient study we defined 6 inclusion-criteria of which the demand of a Braden-score of 20 or lower was repeatedly tested. Even when the study was started, patients were scored again the first day of every new week to measure their risk for developing pressure ulcers. While other studies often recommend the use of a cut-off point of 18, we preferred a cut-off point of 20. Using this cut-off point, Halfens and colleagues⁽²⁰⁾ reported a sensitivity of 73% and a specificity of 70% for scoring pressure-ulcer risk successfully. The advice for a cut-off point of 18 is mainly based on research whereby the criterion "the existence of pressure ulcers versus no pressure ulcers" as predictive outcome value has been used, and not "the risk of pressure ulcers development". The Braden scale is a summated rating scale consisting of six subscales, i.e. sensory perception, activity, mobility, moisture, nutrition, friction and shear. Five of the six subscales are rated from 1 (least favorable) to 4 (most favorable) except friction and shear, which is rated from 1 to 3. Nursing personnel familiar to the patient can perform the rating in less than 1 minute.⁽²¹⁾ To avoid the problem of low inter-rater reliability, we insisted that the same nurse always performed the rating on the same patient.

Data analysis of the R.C.T.

Initially we intended a multi-level analysis because of measurements at the level institutions, wards and patients. However, because not all patients received all three interventions, multi-level analysis would hamper a proper data-analysis. Concerning the possibility of regression analysis, only logistic regression was applicable to our results because of the dichotomous outcome variable. Due to the relatively small sample size, categorical variables sometimes had to be categorized to fulfil the assumption of at least 5 observations at each cell.

Differences between the two intervention periods in the R.C.T.

A logical explanation for the differences between the two intervention periods is difficult to provide. It is possible that the motivation of the participants and the accuracy by which the interventions were performed during the second intervention period were less than in the first intervention period. This can partly be explained by patients and/or relatives that wanted to quit the study, and to some participating health care workers who got tired of performing the intervention as precisely as possible. Therefore, it is questionable if the reliability of the values is as high in the second intervention period as in the first one.

Generalizability of the R.C.T. - results

In spite of a sample population of 79 nursing home residents and some contradictory results in both intervention periods, we can conclude that the results of this study can be generalized to a general nursing home population at high risk for pressure ulcers. Because of our strict formulated inclusion-criteria, one could assume that external validity would be affected. However, these inclusion-criteria were strictly defined in order to include only patients at high risk for pressure ulcers and to ensure that underlying pressure ulcers were not yet developed in other institutions, and would not be a criterion causing any selection-bias. To increase the uniformity of pressure ulcer policy and management between the different nursing homes, we deliberately selected nursing homes which are members of the same pressure ulcer commission (South-East Limburg). However, we were forced to look further than South-East Limburg in order to enlarge the population sample. Therefore, one additional nursing home from outside this region was approached.

Our conclusion that massage does not have an additional beneficial effect in the prevention of pressure ulcers is probably valid for other institutions. As such, it provides support for the Dutch national guidelines, in so far that regular change of position is advisable while massage is not. However, we could not present evidence that massage is definitely harmless. It should be pointed out that our conclusion that effleurages are not harmful is only based on a literature study and on visual observations on the skin, and not on observations in underlying tissues.

4.2 | Regarding the cross-sectional studies of 1991 and 2003 (chapters 4 and 5)

Ecological fallacy

Regarding the cross-sectional study of the 1991 survey and both cross-sectional studies of 2003, we can make comparable remarks. Because of the large samples sizes of individuals participating in these 3 studies and because of the formulated research questions, a cross-sectional design would normally be most appropriate. However, in this way causal relationships can not be investigated, because correlations can only indicate possible relations. As such, only common sense can further indicate in which direction these possible relations may develop. For the two cross-sectional studies of 2003 (see chapter 5), the two data-files were merged after aggregation at the institutional level. This was achieved by using the mean values of all included variables. After aggregation, some correlation coefficients differed from the coefficients before aggregation, although this did not cause a change in statistical outcome. Nevertheless, this should be kept in mind when interpreting aggregated results.

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Generalizability

In chapter 4, we analyzed the results obtained in general and academic hospitals. This contrasts with the two cross-sectional studies of 2003 as presented in chapter 5, in which only general hospitals were taken into account. Therefore, the outcome of these studies can only be generalized to general hospitals-settings. The choice for hospitals instead of nursing homes was based upon the large number of potential participants which are employed in hospitals, and because of the recurrence of the same hospitals in the different studies. Thus, a comparison between different studies was possible.

5 | Implications for practice

At first, the results of our study support the Dutch CBO-guidelines regarding the use of massage in relation to pressure ulcers. This means that

also in our opinion massage can not be considered to be an effective preventive method for the prevention of pressure ulcer development. We would like to stress the following practical recommendations:

1. Do not use massage to prevent pressure ulcers

We were unable to find evidence for preventive effects of massage regarding pressure ulcer development but did also not find conclusive evidence in support for rejection of massage, as the CBO-guidelines suggests. Indeed, no indications were found that massage (i.e. effleurage) was harmful to the skin and its underlying tissues.

This been said, there still exists a gap between theory and practice (chapter 4 and 5). In spite of the different motives to reject massage as a preventive method, we do hope that this research supports the implementation of the CBO-guidelines regarding the use of massage in pressure ulcer prevention.

2. Use regular change of position

As already described in (inter)national literature, supported by statistically significant evidence, and as recommended by several (inter)national guidelines, regular change of body position can help to prevent pressure ulcer development. In combination with this action, we recommend the use of an anti-pressure ulcer mattress. If an anti-pressure ulcer mattress is not available, a patient should be turned over more often than each 6 hours.

3. Do not use DMSO as a preventive method

In spite of the results of our literature review (chapter 3) and a previously performed pilot study⁽⁵⁾, DMSO, topically applicated in concentrations up to 5%, did not show any beneficial effect at all. Therefore, we do not recommend the use of this compound in the prevention of pressure ulcer development.

6 | Recommendations for future research

The fact that massage (effleurage) does not seem to harm the skin can motivate institutions to continue the practice of massage. For instance,

massage can be experienced by the patient as a welcome treatment, and as such it could promote the patients' psychological feeling of well-being. However, one should be well aware of the fact that this has nothing to do with pressure ulcer prevention. In terms of nursing home management, we would advise to quit the practice of massage for the prevention of pressure ulcers, because it has no evident beneficial effects, it saves time, and there can also be a cost-benefit effect for management-teams.

Our results on the effects of DMSO are contradictory to those found by Van Rossum in a pilot study on patients prone to pressure ulcers.⁽⁶⁾ Since it has been shown in earlier studies that DMSO adequately penetrates the skin and even reaches the subcellular level - the site at which OH⁻-radicals are generated - it can be excluded that insufficient penetration is the cause of the inefficiency of DMSO (see chapter 3). Therefore, we reject DMSO as a compound of first choice when considering free radicals as important mediators of the development of pressure ulcers. To elucidate the possible beneficial effects of free radical scavengers, other compounds could be evaluated in detail. Besides ischemia-reperfusion mediated damage on which we focussed, the influence of cell deformation is another interesting pathway for future investigations in the domain of pressure ulcer-aetiology and prevention. The extent to which cells can deform is determined among others, by the strength of proteins belonging to the extra-cellular matrix. Products that may beneficially affect this extra-cellular matrix should be tested as well. In this context, the importance of fundamental research to understand more of the aetiology of pressure ulcers can not be accentuated enough.

Furthermore, it would be easier to analyse collected data from a R.C.T. in which all patients are subjected to all interventions so that more profound (multi-level) analysis can be performed. Randomization at the patient level instead of at the ward level would be an option, but in our opinion not to be advised because it increases the risk of information-bias. A larger population sample can be desirable because it would strengthen any conclusion regarding the absence, c.q. presence of beneficial DMSO effects. Aside from that, a daily visit of the wards would be helpful in motivating, stimulating and controlling the nurses and participating health care givers. From this point of

view, instead of a larger population a small population like 10 per group could also be advantageous. Randomization could be performed at the patient-level, fewer participants should be needed to perform the intervention and it would be better controllable.

In order to further contribute to the evaluation of the bottom-up theory, it would be desirable to take some tissue biopsies before and after treatment of patients prone to pressure ulcers, in order to confirm the conclusion that massage (effleurage) is not harmful to skin and underlying tissues. However, from a deontological perspective, it is questionable whether or not such approach can be justified. Last but not least, studies focussing on preventive methods to decrease pressure ulcer development are surely important for making the existing guidelines more evidence-based and to simplify the implementation-processes of only the effective proven guidelines. Intervention studies, focussing on curative aspects regarding pressure ulcer treatment should also get more attention. Based on the outcomes from fundamental research, these intervention studies must be set up to make nursing practice more evidence-based and to get more insight in the aetiology and pathogenesis of pressure ulcers.

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Research findings published in the literature as well as practical experience show that there is great confusion over the question whether massage prevents the development of pressure ulcers (PU). Some nurses are still fully convinced of the value of massaging to prevent pressure ulcers, notwithstanding conflicting national and international guidelines. Others completely reject this method. Regardless of published guidelines, both groups consider their opinions to be based on arguments from the research literature.

This thesis reports on a research project that objectively examined the effect of massage on the prevalence of pressure ulcers. The project first examined the effects of massaging in general, after which it focused on massaging as a method to prevent pressure ulcers. In addition, a prior study had raised the expectation that massaging with a cream containing a radical scavenger might be more effective than massaging with an indifferent cream. Hence, we studied the available literature on the effects of such a radical scavenger, dimethyl sulfoxide (DMSO), before starting an experiment to empirically compare massaging with and without DMSO.

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We combined the findings of two studies assessing the knowledge of, beliefs about and actual use of massage to prevent pressure ulcers among nurses, dating from 1991 and 2003, and compared their results with the Dutch guidelines prevalent at the time. The outcome reconfirmed the existing discrepancy between theory and practice.

The Introduction to this thesis (*Chapter 1*) discusses the background to the problem of pressure ulcers, by outlining the physiology and blood supply system in healthy skin and the aetiology and pathogenesis of pressure ulcers. Since there is as yet no consensus on the latter, several competing explanatory models of the origin and development of pressure ulcers are discussed.

Since we wanted to use one unequivocal definition of pressure ulcers, we adopted the definition proposed by the European Pressure Ulcer Advisory Panel (EPUAP), and the corresponding system of 4 degrees of severity. Chapter 1 also explains why the research centred on the effect of massage to

prevent pressure ulcers, and why the use of DMSO was investigated. The chapter ends by stating the overall goals of the research project reported on in this thesis and surveys the content of the thesis.

Chapter 2 describes a literature study into massage in general and its use as a potential method to prevent pressure ulcers in particular. The art of massage is an ancient one: texts dating from before 2000 BC refer to the healing effect of rubbing a person's body with one's hands. Much research has been done and published into the mechanical, psychological and relaxing effects of massage. This chapter surveys the various manual massaging techniques, with their indications and contraindications. It then goes on to discuss the clinical and physical aspects of pressure ulcers, the physiology of the skin, the extrinsic and intrinsic factors affecting the development of pressure ulcers and the relations between 'time' and 'pressure' and their effects on the interstitial fluid compartments. Knowledge of massage techniques and of the causes and development of pressure ulcers has led to the conclusion that the only massage technique that might be appropriate is effleurage, which imposes minimal strain on the skin and underlying tissues.

Chapter 3 presents the findings of a systematic survey of the literature on the effects of topical application of dimethyl sulfoxide (DMSO) on the skin in terms of wound healing and as an anti-inflammatory agent. Pressure ulcer development involves the formation of free radicals (as indicated, for instance, in the theory of ischemia-reperfusion damage). The most important of these free radicals are the superoxide anion ($O_2^{\cdot-}$), hydrogen peroxide (H_2O_2) and the hydroxyl radical ($OH^{\cdot}$). It has been suggested that radical scavengers might slow down the development of pressure ulcers or even help prevent them, by eliminating harmful radicals. One such radical scavenger, which specifically eliminates the hydroxyl radical, is DMSO. A prior study among a population of nursing home residents at high risk of pressure ulcers had found favourable effects of DMSO on reversing pressure ulcer development. Our literature study tried to identify the potential favourable effect of DMSO on wound healing and inflammatory mechanisms, and the dosages required for such effects. Based on the literature findings, and those of the prior study, we decided that adding 5% DMSO to an indifferent cream should be

enough as an active ingredient. This concentration was also assumed to cause no harmful side effects like erythema and itching.

Chapter 4 surveys the existing knowledge among Dutch nurses about massaging as a potential method to prevent pressure ulcers, as well as their beliefs about favourable effects of massage for this purpose and their actual use of massage to prevent pressure ulcer development. Data sets from two previous cross-sectional studies were compared. The first of these studies dates from 1991 and involved interviews with 373 nurses, while the second dates from 2003 and included 529 nurses. We assessed whether there were any differences between these two populations as regards knowledge, beliefs and practice, and whether their knowledge, beliefs and practice corresponded with the guidelines prevalent in each of these periods. The results showed that the nurses in 2003 were 'doing better' than those surveyed in 1991. At the same time, it became clear that the official Dutch guidelines were still insufficiently being implemented by nurses.

Chapter 5 discusses the findings in greater detail, by linking the data from the 2003 cross-sectional study to those of another cross-sectional study from the same year, the National Prevalence Study of Pressure Ulcers (Bours *et al.*). All data were analysed at aggregated institutional level (i.e. that of general hospitals), which we hoped would yield information on possible relations between nurses' knowledge, their behaviour in practice and the national guidelines on the one hand, and the actual prevalence data on the other. We also assessed whether an institute's pressure ulcer policy was related to nurses' knowledge and the prevalence of pressure ulcers. As expected, knowledge and practical behaviour among nurses were highly correlated. However, neither knowledge nor practical behaviour appeared to be related to actual prevalence data obtained from surveys. These findings partly support those of the study reported on in *Chapter 6*. Some of the quality indicators that help determine an institute's pressure ulcer policy do appear to have some impact on the prevalence rates.

Chapter 6 describes the results of a randomised controlled trial we undertook to assess two main questions:

(1) Does massaging with an indifferent cream every six hours, combined with

repositioning on an anti-PU mattress, have a preventive effect on the development of pressure ulcers among patients at high risk of such ulcers (as indicated by a Braden score of 20 or lower), compared with a similar group receiving only position changes every six hours?

2) Does massaging with a cream containing DMSO every six hours, in combination with repositioning on an anti-PU mattress, have a preventive effect on the development of pressure ulcers among patients at high risk of such ulcers (as indicated by a Braden score of 20 or lower), compared with a similar group receiving either massage with an indifferent cream combined with repositioning or repositioning alone (both administered every six hours)?

The results of the trial allow the unequivocal conclusion that massaging does not contribute to the prevention of pressure ulcers. On the other hand, they also show that massaging in the form of effleurage does not appear to be harmful, as has often been suggested in the literature. Contrary to our hypothesis, DMSO was found to have an unfavourable effect on pressure ulcer development.

Chapter 7 outlines the main findings of the various studies and presents some methodological and theoretical reflections on these findings. The methodological reflections focus on the RCT design we used, the justification of the Braden scale cut-off point we chose and the generalisability of our RCT results and those of the two combined cross-sectional studies. The theoretical reflections try to establish the social relevance of the studies and briefly outline existing theories on the development of pressure ulcers insofar as they are relevant to the present research. The chapter ends by discussing the implications of our findings for nursing practice and providing recommendations for further research.

Uit de literatuur én in de praktijk blijkt dat er grote verwarring bestaat over een al dan niet preventief effect van massage bij de ontwikkeling van decubitus (drukwonden). Daar waar de ene verpleegkundige, ondanks tegenstrijdige (inter)nationale richtlijnen zweert bij massage ter preventie van decubitus, verwerpt de andere het helemaal. Los van de voorgeschreven richtlijnen menen beiden hun mening te kunnen baseren op argumenten aangevoerd vanuit de wetenschappelijke literatuur.

In dit proefschrift wordt het effect van massage op het voorkomen van decubitus onderzocht. Allereerst zijn de effecten van massage in het algemeen in kaart gebracht, om vervolgens meer specifiek te kijken naar massage als preventieve activiteit bij decubitus. Naar aanleiding van een eerder verricht vooronderzoek werd bovendien verwacht dat massage met een crème waaraan een radicaal-scavenger (= radicaal-wegvanger) was toegevoegd een meerwaarde zou kunnen hebben. Vandaar dat ook een literatuurstudie is verricht naar de effecten van de radicaal-scavenger dimethyl sulfoxide (DMSO) alvorens een experiment op te zetten waarin massage met én zonder DMSO empirisch getoetst werd.

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Twee studies, respectievelijk van 1991 en 2003, die de kennis van-, het geloof in- en de toegepaste praktijk van massage in decubituspreventie onder verpleegkundigen onderzochten, werden aan elkaar gekoppeld. Hun uitkomsten werden vergeleken met de geldende CBO-richtlijnen. Op basis hiervan werd de bestaande discrepantie tussen theorie en praktijk nogmaals bevestigd.

In de introductie van dit proefschrift (hoofdstuk 1), wordt de achtergrond van het decubitusprobleem besproken. Daartoe wordt de fysiologie en de bloedvoorziening van de gezonde huid geschetst, om vervolgens de etiologie en pathogenese van decubitus toe te lichten. Omdat hierover geen consensus heerst zijn er verschillende verklaringsmodellen voor het ontstaan en de ontwikkeling van decubitus. Deze worden allen beschreven.

Om een eenduidige definitie van decubitus te hanteren is gekozen voor de definitie en het daarbijhorende 4-gradensysteem van het European Pressure Ulcer Advisory Panel (EPUAP). In hoofdstuk 1 wordt verder toegelicht waarom het effect van massage in relatie tot decubituspreventie het centrale thema

is in dit proefschrift, en waarom uiteindelijk ook voor het gebruik van dimethyl sulfoxide werd gekozen. Er wordt afgesloten met de beschrijving van het uiteindelijke doel van deze thesis en met een overzicht van de inhoud en opbouw ervan.

Hoofdstuk 2 beschrijft de literatuurstudie naar massage in zijn algemeenheid en meer specifiek naar massage als mogelijk preventief middel voor decubitus. De kunst van het masseren is niet nieuw. In geschriften van vóór 2000 voor Christus wordt er reeds melding gemaakt van het helende effect van het wrijven met de handen. Er is heel wat onderzoek verricht en gepubliceerd over de mechanische, psychologische en relaxerende effecten van massage. De verschillende manuele technieken van massage zijn in dit hoofdstuk in kaart gebracht, evenals de indicaties en contra-indicaties van deze technieken. Vervolgens worden de klinische en fysische aspecten van decubitus besproken, de fysiologie van de huid, de extrinsieke- en intrinsieke factoren van invloed op decubitusontwikkeling, en de relatie tussen 'tijd' en 'druk' en hun effect op de interstitiële vloeistofcompartimenten. Op basis van de kennis over massage en de kennis omtrent het ontstaan en de ontwikkeling van decubitus is geconcludeerd dat als massage dient gebruikt te worden, men zich dient te beperken tot de effleurage-techniek teneinde de huid en onderliggende weefsels zo min mogelijk te belasten.

Hoofdstuk 3 beschrijft het systematisch onderzoek van bestaande literatuur rond de effectiviteit van dimethyl sulfoxide (DMSO) op wondheling enerzijds en als anti-inflammatoir middel anderzijds, en dit bij lokale aanbrenging op de huid.

De ontwikkeling van decubitus gaat gepaard met de vorming van vrije radicalen (zie o.a. de theorie van de ischemie-reperfusie schade). De belangrijkste vertegenwoordigers van deze radicalen zijn het superoxide anion ($O_2^{\cdot -}$), waterstof peroxide (H_2O_2) en het hydroxyl radicaal ($OH^{\cdot}$). De idee bestaat dat radicaal-scavengers de ontwikkeling van decubitus zouden kunnen afremmen of zelfs kunnen helpen voorkomen via het wegvangen van de schadelijke radicalen. Eén van zulke radicalen-wegvangers, specifiek inwerkend op het hydroxyl radicaal, is DMSO. Een eerder verricht vooronderzoek bij een in een verpleeghuis verblijvende hoog-risico populatie voor decubitus toonde gunstige effecten van DMSO aan op het terugdringen van decubitusontwikkeling. Met deze

literatuurstudie is nagegaan in welke mate en in welke hoeveelheid DMSO mogelijk een invloed heeft op wondheling en op ontstekingsmechanismen. Op basis van dit onderzoek en het voorafgaande vooronderzoek is besloten dat 5% DMSO, toegevoegd aan een indifferente crème, voldoende moest zijn als werkzame substantie. Bovendien zou deze concentratie geen aanleiding geven tot het optreden van schadelijke nevenwerkingen zoals roodheid en jeuk.

Hoofdstuk 4 brengt voor de Nederlandse verpleegkundigen de stand van zaken in kaart betreffende hun kennis omtrent massage als een al dan niet werkzaam preventief middel voor decubitus, hun geloof in de eventueel heilzame werking van massage als preventief middel en de effectief uitgevoerde praktijk van het masseren van patiënten ter preventie van decubitusontwikkeling. Van twee cross-sectionele studies die in het verleden uitgevoerd werden, werden de data-sets gekoppeld. De eerste studie dateert van 1991 (373 ondervraagde verpleegkundigen), de tweede studie van 2003 (529 ondervraagde verpleegkundigen). Er werd enerzijds getoetst op verschillen tussen beide populaties betreffende kennis, geloof en praktijk, en anderzijds op de mate van overeenkomsten met de richtlijnen uit de betreffende perioden. De resultaten geven aan dat de verpleegkundigen van 2003 het 'beter' doen dan deze van 1991. Desondanks blijft het duidelijk dat de CBO-richtlijnen nog steeds niet voldoende zijn doorgedrongen zijn tot op de werkvloer.

Hoofdstuk 5 gaat nog dieper in op dit onderzoek. Hiertoe werd de data van de cross-sectionele studie van 2003 gekoppeld aan de data van een andere cross-sectionele studie uit 2003, namelijk het Landelijk Prevalentie Onderzoek Decubitus (LPOD) (Bours *et al.*). Hierbij werden alle gegevens op geaggregeerd instellingsniveau (i.e. algemene ziekenhuizen) geanalyseerd. We hoopten hiermee inzicht te krijgen in het al dan niet bestaan van relaties tussen de kennis van verpleegkundigen, de uitgevoerde praktijk en voorgeschreven CBO-richtlijnen enerzijds en de uiteindelijk gemeten prevalentie-cijfers anderzijds. Tevens werd nagegaan of het decubitusbeleid van een instelling samenhang met de kennis van verpleegkundigen en de gemeten prevalentie van decubitus. Zoals verwacht bleek dat de kennis van- en de toegepaste praktijk door verpleegkundigen sterk met elkaar correleren. Kennis noch praktijk echter lijken een verband te tonen met de uiteindelijke gemeten prevalentie-cijfers. Een uitkomst die de uiteindelijke resultaten van de studie in hoofdstuk 6 voor een

stuk zal onderschrijven. Enkele kwaliteitsindicatoren die mee het decubitus-beleid van een instelling bepalen lijken wel enigszins van invloed op het gemeten prevalentiecijfer.

Hoofdstuk 6 beschrijft de resultaten van onze uitgevoerde R.C.T. (randomized controlled trial) waarin twee hoofdvragen centraal stonden:

1) Heeft massage met een indifferente crème, uitgevoerd om de zes uur in combinatie met wisselgigging op een anti-decubitus matras, bij hoog-risico patiënten voor decubitus conform een Braden-score van 20 of lager, een preventief effect op het ontstaan van decubitus, vergeleken met éénzelfde groep die echter enkel wisselgigging om de zes uur kreeg toegepast?

2) Heeft massage met een DMSO-bevattende crème, uitgevoerd om de zes uur in combinatie met wisselgigging op een anti-decubitus matras, bij hoog-risico patiënten voor decubitus conform een Braden-score van 20 of lager, een preventief effect op het ontstaan van decubitus, vergeleken met éénzelfde groep die echter óf massage met een indifferente crème gecombineerd met wisselgigging kreeg, óf enkel wisselgigging kreeg (beiden eveneens om de zes uur)?

De gevonden resultaten leiden tot de éénzijdige conclusie dat massage niet bijdraagt aan de preventie van decubitus. Evenwel tonen zij ook aan dat massage, uitgevoerd als effleurages, niet schadelijk lijkt te zijn zoals vaak beweerd wordt in de literatuur. In tegenstelling tot de gestelde hypothese bleek DMSO echter een negatieve invloed te hebben op de decubitusontwikkeling.

In *hoofdstuk 7* worden de belangrijkste bevindingen van de verschillende studies beschreven en onderworpen aan methodologische en theoretische reflecties. De methodologische reflectie spitst zich o.a. toe op de keuze van het door ons gehanteerde R.C.T.-ontwerp, de verantwoording voor het gekozen afkappunt bij de Braden-schaal, de generaliseerbaarheid van de R.C.T.-resultaten en die van de gekoppelde cross-sectionele studieresultaten. De theoretische reflectie wil de maatschappelijke relevantie van de studie aantonen en belicht kort de twee bestaande theorieën voor de ontwikkeling van decubitus in het kader van ons onderzoek. Als laatste worden de implicaties van deze studie voor de praktijk besproken en worden aanbevelingen gegeven voor toekomstig wetenschappelijk onderzoek.

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Gerrie Bours
Heidi Breuker
Kris Joosten

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Ine Smeets	Maria van der Heyden
Lia Rijswijk	Collegae ZW-VW

Buiten categorie

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| Curriculum Vitae |

Personal |

Name Inge G.P. Duimel-Peeters
Date of birth September 9, 1974
Place of birth Tongeren, Belgium

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Education / work |

1995-1998 Bachelor Programme Physiotherapy
Provinciale Hogeschool Limburg, Hasselt (B)
Thesis: Research and treatment of urine-incontinence pre- and post-partum [In Dutch].

1998-2001 Master Programme Health Sciences,
Main Subject: Movement Science,
Faculty of Health Sciences, Universiteit Maastricht (NL)
Thesis: The effect of two plant abstracts on the cell cycle kinetics and induction of apoptosis by the HCl-II cell line.
(Department Molecular Cell Biology and Genetics, Faculty of Medicine, UM).

- 2001- 2004 Post-doctoral Master Programme Epidemiology
EMGO-institute / Department of Clinical
Epidemiology and Biostatistics.
Medical Center, Vrije Universiteit Amsterdam (NL)
*Main subjects: Cancer Epidemiology, Public
Health Epidemiology, Prevention - and Incidence
Research*
- 2001 - May 2005 PhD Programme
Faculty of Health Sciences
Department Health Care Studies / Section
Nursing Science
Universiteit Maastricht (NL)
This doctoral thesis.
- May - Sept. 2005 Researcher on the 'Resultaten Scoren'-project
GGZ Nederland, Amersfoort (NL)
- Oct. 2005 - present Staff Advisor Methodology
Ministry of Health, Welfare and Sport
Dutch Health Care Inspectorate, Utrecht (NL)

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