

Good Gargling

managing oral conditions using essential oils

**Presentation to Botanica2012
Trinity College Dublin**

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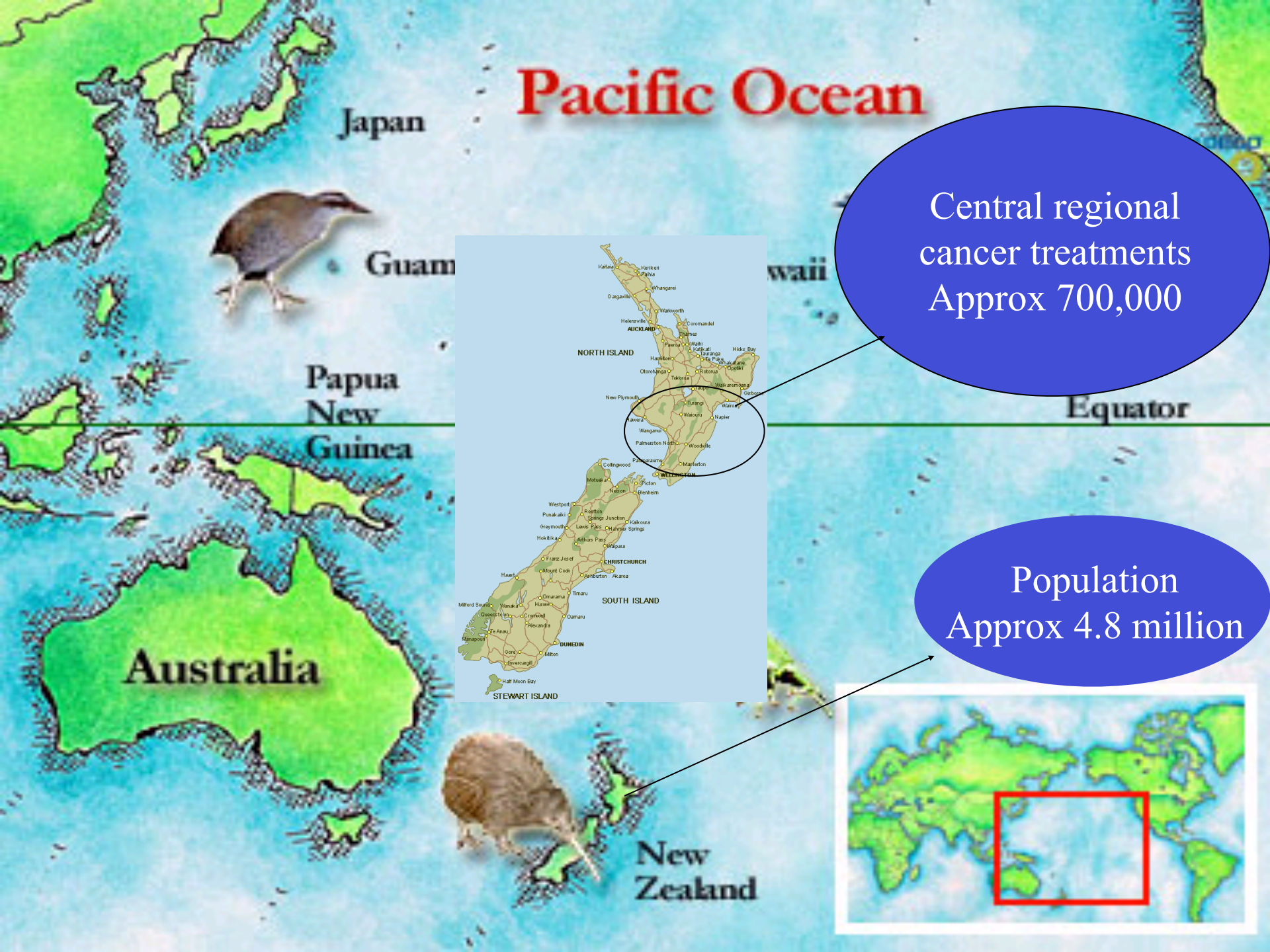
Introduction

- As a registered nurse Wendy has been Involved in health and aromatics since 1983
- Currently runs natural skin care company using range of aromatic extracts
- Actively involved in health promotion as a RN
- NZ's first research at doctoral level exploring therapeutic effects of essential oils
- Prior to completing clinical research the radiotherapy department was used as a clinical environment for massage and aromatherapy students
- Conducted 3 x mini research projects to evaluate the benefits to the patients and to the students as a learning experience



Good Gargling

- Clinical trial evaluating the effects of an essential oil mouth wash using Kanuka and manuka essential oils during radiotherapy
- This study was completed as part of the requirements for the completion of the Doctorate in Health Science-full acknowledgements and references can be obtained from www.aromaticadventures.com



Pacific Ocean

Japan

Guam

Papua
New
Guinea

Australia

New
Zealand

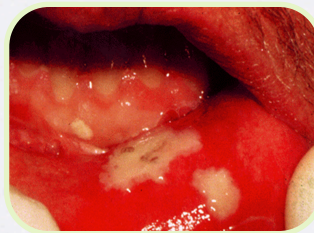
Central regional
cancer treatments
Approx 700,000

Population
Approx 4.8 million



Good Gargling *an investigation into the effects of an essential oil mouthwash on radiation induced mucositis (RIM) for head and neck (HAN) patients*

- Research was part of requirements for Doctorate Health Science Degree and underwent full ethical approval (4 committees)
- I conducted research as an 'observer' in the dept. I am not an expert in radiation therapy
- Prior to research spent 3 years in dept. with massage/aromatherapy students to build rapport with staff and understand cancer treatment
- RIM- expected in 80-100% of patients-Definite point in treatment where reaction occurs (pain)
- RIM affects QOL, treatment due to pain, poor nutrition, stress, fatigue etc



What Happens with Head and Neck (HAN) Radiotherapy Patients?

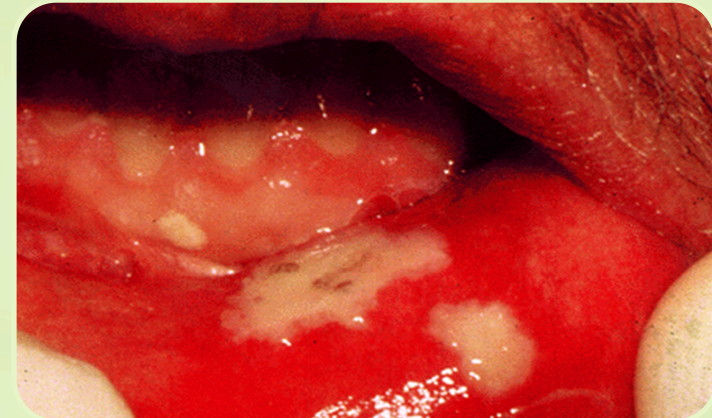


1. Purpose built mask made for marking treatment site so face is not masked.

4. Percutaneous endoscopic gastric (PEG) feeding tube for nutritional support when too painful to eat and weight loss >15%



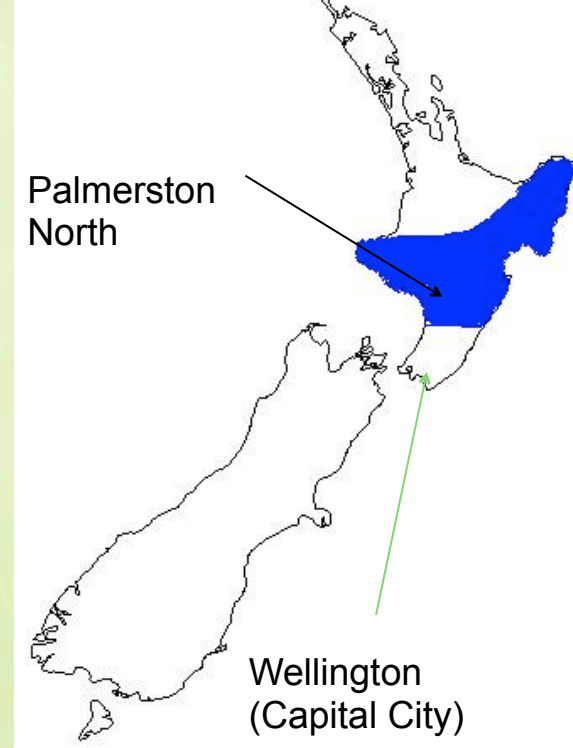
2. All treatment given via a linear accelerator in daily fractions for 20-25 treatment days (5 days per week)



3. Confluent mucositis with severe ulceration on tongue and lips causing severe pain, taste changes, altered speech, 80-100% of patients develop mucositis

Pilot Study Design

- Randomised, placebo controlled, double blind clinical trial using a convenience sample of 25 (+1) patients who met inclusion criteria
- Participants-All adults
 - Having non-palliative RT which included the OP area
 - Physically able to gargle
 - Able to keep a diary
 - Able to give informed consent
 - Recruited from the Regional Cancer Treatment Services (RCTS) lower North Island, New Zealand with consultant consent



	Active	Placebo	Control
Age 45-60	1	0	4
Age 61-75	2	5	2
Age >75	3	1	1
Male	5	2	7
Female	1	4	0
≤5600 cGy	2	3	3
≥5800 cGy	4	4	3

Central North Island of New Zealand-catchment area for the RCTS (pop. 540,000. 1200 patients treated per year with HAN patients accounting for 7-9%)

Interventions

- **Active gargle/swallow-** combination of manuka and kanuka essential oils mixed with water at time of use + *usual oral care (baking soda mouthwash and analgesia as required)*
- **Placebo** gargle sterile water mixed with water at time of use + *usual oral care*
- **Control-**no additional gargle + *usual oral care*
- **Gargling Protocol-**
 - Gargling commenced on or up to 2 days before RT
 - 5 drops of blend of essential oils or placebo were added to 15 ml warm tap water and gargled around the mouth for at least 15 seconds then discarded then a second solution prepared and swallowed
 - On radiation days gargle occurred up to 5 times (including pre and post radiation)
 - On rest days (2 per week) gargling occurred for 3 x per day
 - Gargling continued for one week post treatment
 - Each patient used 30 ml in total of placebo or active gargle solution + additional warm water

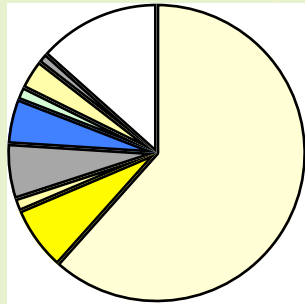


The Essential oils



Kanuka-Kunzea ericoides
South Island New Zealand

K. ericoides

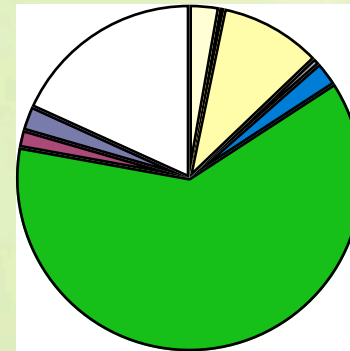


- alpha pinene
- beta pinene
- other mon-terpenes
- limonene
- 1,8, cineol
- terpinen-4-ol
- other alcohols
- sesquiterpenes
- gamma terpinene
- alpha terpinene
- leptospermone
- viridifloral
- alpha terpineol
- beta-triketones
- other constituents

Manuka-Leptospermum scoparium, South Island New Zealand



L. scopiarum



- alpha pinene
- beta pinene
- other mon-terpenes
- limonene
- 1,8, cineol
- terpinen-4-ol
- other alcohols
- sesquiterpenes
- gamma terpinene
- alpha terpinene
- leptospermone
- viridifloral
- alpha terpineol
- beta-triketones
- other constituents

These 2 oils were selected after comparing analyses of 11 different oils grown around New Zealand. The desired effects of **radioprotection** (attributed to viridifloral), **analgesic** and **anti-inflammatory** actions (attributed to sesquiterpenes) were hypothesised to be present with these constituents in the combination of oils. Neither oil had any toxic constituents. No other studies have explored the use of these oils in this way so there was no previous clinical data to evaluate. Both oils were from the same distiller and all patients used oil from the same batch. This research did not explore the role of microbes in mucositis therefore anti microbial actions related to beta triketones were not required. Beta triketones are higher in oils grown in the North Island but do not have the viridifloral and sesquiterpenes present.

Outcomes Measured

- Objective measurement of RIM by doctor (weekly using scale as per table)
- Subjective scoring of pain and recording of analgesia use (5 x day by patient using MidCentral Health 0-10 pain scale + recording each dose of medication)
- Objective weight measurement (weekly by nurse measured in kg)
- Subjective recording of quality of life factors-fatigue, taste, secretions, memory problems (daily by patient 0-10 scale)

Grade	Oropharyngeal reaction	Oral cavity reaction
0	Odynophagia	-
1	Mild dysphagia	Erythema, mild pain, nil analgesia
2	Moderate dysphagia, liquid diet, requiring narcotic analgesia	Patchy mucositis, inflammation, pain 5+/10
3	Severe dysphagia, >15 % weight loss, artificial feeding and/or hydration	Confluent mucositis, narcotic analgesia
4	Complete obstruction or ulceration	Complete ulceration, haemorrhage or necrosis

Regional Cancer Treatment Services (Palmerston North, NZ) assessment scale of Radiation Induced Mucositis (RIM).

Active	Placebo	Control
5 drops 50:50 blend K+M in 30 mls warm H2O 5 x day gargle PLUS SAME swallow	Sterile water + warm water gargle + swallow	No additional treatment
Usual cares* as per consultant wishes	Usual cares* as per consultant wishes	Usual cares* as per consultant wishes

- Objective RIM (0-5 scale) assessed by medical staff
- Pain scoring 5 x day (0-10 scale) + recording of analgesia usage
- Objective weekly weight (clinical staff)
- Subjective QOL (0-10 scale)

Subjective Quality of Life Scoring

Scoring for symptoms developed for trial (0-10)

Score	Descriptors
0	Not feeling the symptom at all;
1-3	Feeling symptom mildly and infrequently, not affecting their day to day activities;
4-6	Felt symptom often, moderately intensely and starting to affect day to day activities:
7-9	Feeling symptom every day, could barely function through the day or perform daily activities
10	Symptom overwhelmed the patient.

Symptoms experienced to score

	Group of symptoms
Eating	All food tastes same, foul taste of food, inability to eat solid food, lack of taste, loss of appetite,
Pain and discomfort	Pain when eating, sore throat, pain when not eating
Fatigue and memory loss	Loss of concentration, memory loss and fatigue.
Lack of secretions	Dry cough, dry mouth, not enough mucous or saliva.
Excess secretions	Too much saliva or mucous, nausea and vomiting,

Results and data analysis of the 19/26 patients who completed treatment

Compared results between research groups plus considered other treatment and patient factors

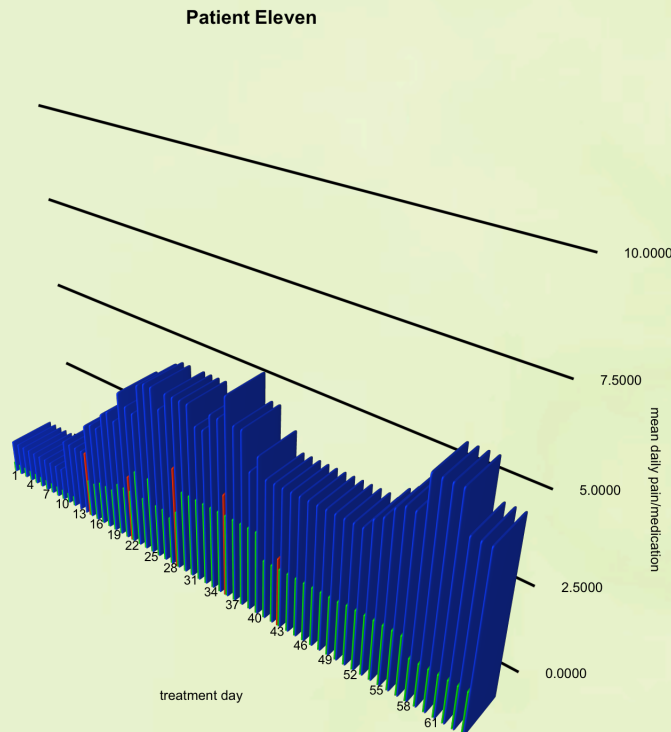
Treatment variables: total cGy dose; site; surgery; chemotherapy; PEG; teeth extraction.

Patient variables: gender; age, smoking, presence of family member (s)

Active gargle compliance >90%

Placebo gargle compliance 80-90%

Sample Individual patient Graph



Each patient had a graph made which showed the mean daily pain scores (blue), medication use (green) and the weekly mucositis scores (red). This shows that pain increased in response to the mucositis and medication use also increased (patient 11). Pain also remained after treatment continued

Outcome 1: Development of RIM

- Maximum score (0-4) over treatment
- Results
 - All patients developed mucositis to some degree (range 1-3/4)

RIM score (0-4)	Appearance	Number of patients
1	Redness +/-pain	6
2	Ulcer + pain	12
3	Multiple ulcers, treatment halted	1

Radiation Dose when mucositis first appeared

	Active (n=6)	Control (n=7)	Placebo (n=6)
cGy (total received at point RIM first recorded)	3120 (SD=1136)	2136 (SD=907)	1450 (SD=661)
Treatment days	15.6	10.68	7.25

The Active gargle group went the longest time until experienced first reaction ($p=0.05$) (Tukey's post hoc test for Honest Significant Difference. The generally accepted threshold for developing mucositis is between 1500-2000 cGy (Scully *et al.* 2003; 2004)

Outcome 2: The experience of pain

- Mean daily pain scores (0-10 scale). Patients rated their oral pain before and after gargling, radiotherapy and before each meal.
- Mean daily oral care medication and analgesia-this included baking soda mouthwash, anti fungal drops, anaesthetic spray or lozenges, NSAIDS, mild and other analgesia. No patients were taking analgesia for other problems
- cGy pain score first $\geq 3/10$ (mild to moderate and would start taking paracetamol)
- Impact of pain on QOL (0-10) scale where patients recorded how much pain affected them or stopped them doing things.



Reproduced with permission MidCentral Health Pain Services, PN, New Zealand

Analysis of Pain Experience

Not all patients experienced by pain. Sample size too small to draw statistical conclusions from.

General observations:

When pain reached 3/10 it preceded the appearance of mucositis by a mean of 7 days

Those patients who used the active gargle experienced less severe pain and for less time compared to the control and placebo groups however any differences between groups did not reach significance.

There appears to be correlation between the act of gargling and the perception as to the effect of pain on quality of life,

Active gargle patients reported they felt the Active gargle had a soothing and coating effect.

No side effects experienced at all.

Less patients in the active developed pain of $\geq 3/10$

Pre radiotherapy surgery, teeth extraction, age and gender did not impact on pain experience

Most pain had gone by 2 week follow up-there is a definite point around day 10 after treatment that patients feel "they have turned the corner".

Number of patients who experienced pain of $\geq 3/10$

- Mild analgesia (paracetamol) use
 - ACTIVE group required 50% less paracetamol over total treatment compared to placebo and control groups
- Local anaesthetic (LA) agents- no ACTIVE groups required LA agents

Effects on nutritional outcomes

Active group had lowest overall percentage of weight change over baseline but not significant
Wide variations in taste and secretions alterations and the impact on QOL but most not significant
Whilst dry mouth was a problem for most patients the severity and impact was not worsened by longer radiotherapy ($\geq 5600\text{cGy}$ $p=0.019$). The social aspect of eating was also apparent in the data collection, however data was not formally collected. The presence of family members as well as being part of the 'communal' accommodation boosted their ability to eat. If patients fitted into the 'social' structure or culture there and enjoyed shared meals and being 'jollied' along they seemed to do better. For those patients though that did not have family members and felt they did not fit in at the Cancer Society house they really struggled to eat. One patient was so depressed he contemplated suicide.

In conclusion

- This pilot study demonstrated that an active manuka/kanuka mouthwash gargled during radiotherapy treatment did significantly delay the development of radiation induced mucositis ($p=0.05$)
- Due to the small sample size it was not possible to determine whether this reduction in time with RIM had an impact on pain experience, nutritional status and quality of life
- There were no adverse events associated with the mouthwash and it was generally well tolerated
- This study is worthy of replication with a larger sample size (post hoc analysis indicates up to 60 patients are needed to determine difference in some of the variables)
- Larger study could -
 - Explore role of microbes
 - Measure salivary lactoferrin as an indicator of effect

Acknowledgements....

- This study was conducted by Wendy Maddocks-Jennings as partial fulfilment for the degree of Doctor Health Science under the supervision of Dr's. Wilkinson, Shillington and Cavanagh.
- A heart felt thank you to all patients who willingly participated in extensive data collection
- Thank you to Regional Cancer Treatment Services New Zealand for the access to the department for 6 months to collect data and reviewing material.

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Other Uses for essential oils on the oral mucosa

- Made up of epithelial tissue- 3 different types covering the tongue and cheeks
- Mucosa secrete mucous (but not all do)
- Mucous acts by trapping pathogens so is a protective membrane
- Anything that destroys the mucosa increases risk of infection

- Everyday oral hygiene-anti bacterial- prevent problems occurring including halitosis
- Rose oil
- Peppermint or spearmint oil
- +/- antiseptic oil such as tea tree/manuka/cajeput
- Cardamon oil (cardamom seed or caraway)
- Research peppermint/tea tree/lemon (Intensive Care patients) Dr. Myung-haeng Hur, Maddocks-Jennings et al

Common Conditions of the Oral Mucosa

- Mouth ulcers- commonly due to trauma (dentures/fillings etc) but **MUST** be checked if there for more than 3 weeks- ? malignancy
- May also be due to vitamin or mineral deficiency, HIV, Chronic auto immune disorders
- May be due to infections- herpes/chicken pox/ hand-foot-mouth/ fungal infections
 - EO treatment- anti bacterial/healing/analgesic (Fragonia, Manuka, tea tree, lemon (anti viral)
 - Double the effect by using corresponding hydrosol if possible or TEA TREE hydrosol as base

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