DYSPHAGIA AND ORAL HEALTH: IMPLEMENTING A MODIFIED FREE-WATER PROTOCOL IN LONG-TERM CARE – FIRST DO NO HARM

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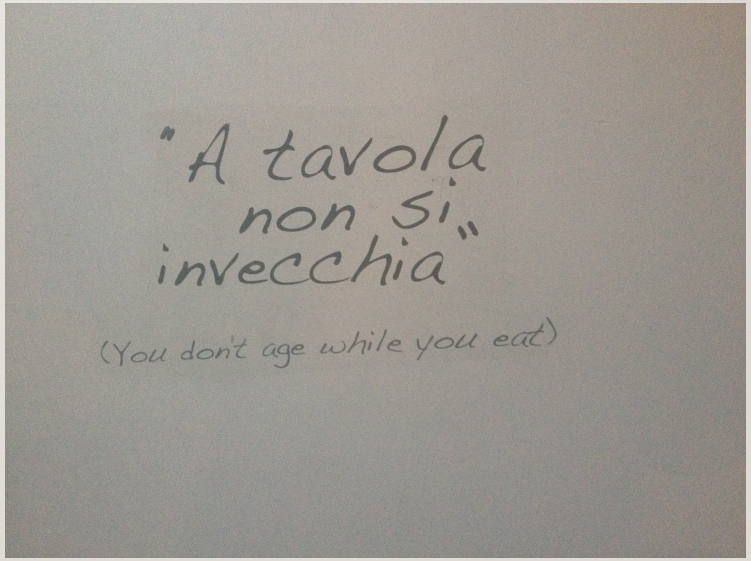
SETTING THE FRAME – THE BIG PICTURE

"While there is life, we must provide quality of life"
-Paul Raia



Tristani, M (2016) Perspectives of ASHA SIG 15, Vol. 1 Part 3 ASHA

AGENDA

- **Topics to be discussed**
- Ethical and Practical Challenges for studying this population
- Background for the Study - Relevance
- The Research question(s)
- Methods - Modifications
- Results and Limitations

- **Key Messages – Lessons learned**
- Tenacity for overcoming obstacles
  - "too hard bucket"
- Critical Stakeholder Alignment
  - Champion for dealing with the Realities
- Essential to keep 4-Ethical Pillars in mind

Presentation Objective: Enhanced knowledge for where research meets reality

PILLARS OF ETHICAL PRACTICE

In Healthcare

In Research

- **Autonomy, *respect* for self-determination**
  - **Choice, consent, assent, privacy**
- **Beneficence, duty to do *good***
  - **Providing the right care at the right time for the right person. Positive outcome.**
- **Nonmaleficence, duty to not cause *harm***
  - **First do no harm: criminally intended to harm, along continuum to unintentional negligence.**
- **Social justice, equality and equity.**
  - **Discrimination due to race, sex, gender, age, and other -isms**
  - **Distribution of healthcare resources (research)**

PILLARS OF ETHICAL PRACTICE

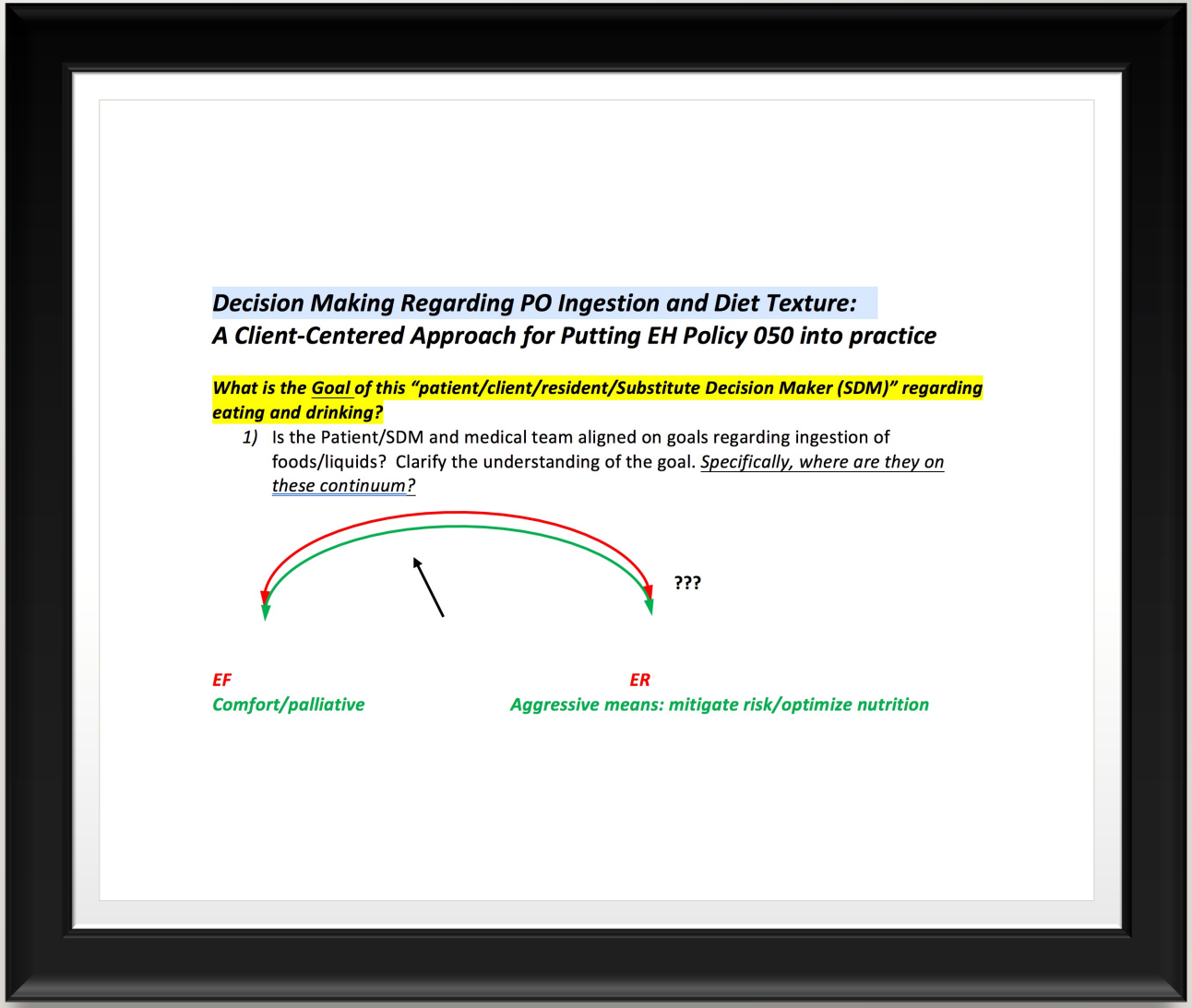
Healthcare - EH Policy

Research - HREB

- **Autonomy, respect for self-determination**
  - **Informed Choice: the patient/family wishes/goals for living and dying.**
- **Beneficence, duty to do *good***
  - **Providing the right care at the right time for the right person. Positive outcome.**
- **Nonmaleficence, duty to not cause *harm***
  - **First do no harm: No negative effects on health & not distressing to patient and family.**
- **Social justice, equality and equity.**
  - **Discrimination due to race, sex, gender, age, and other -isms**
  - **Distribution of healthcare resources (research)**

"INFORMED" CHOICE: VALUES & TRADEOFFS

- Desire normalcy and comfort for eating and drinking - Extreme Freedom (EF)
- Desire optimally safe - Extreme restriction (ER)
- Issues: AHCD and SDMs



Decision Making Regarding PO Ingestion and Diet Texture:
A Client-Centered Approach for Putting EH Policy 050 into practice

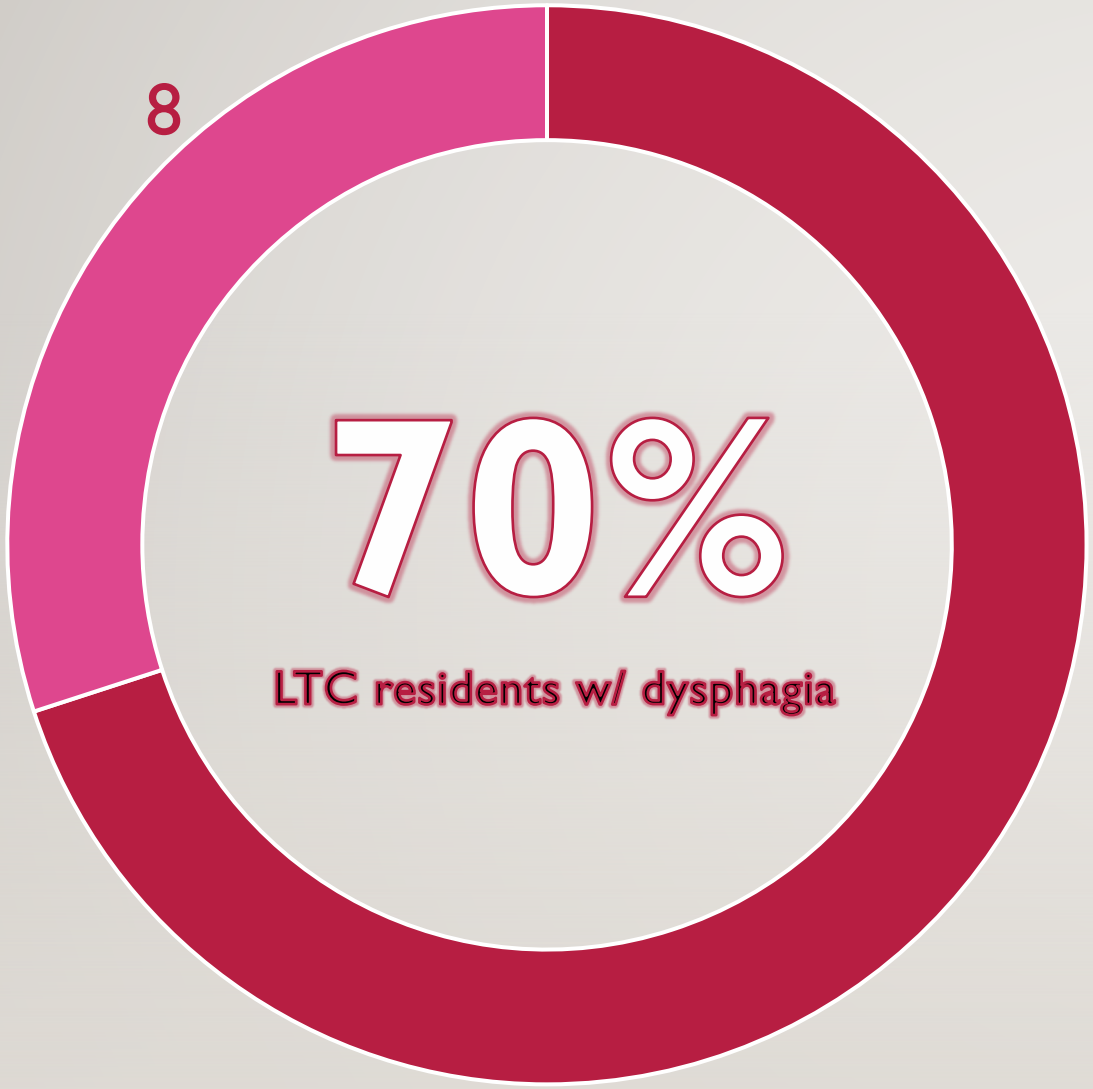
What is the Goal of this "patient/client/resident/Substitute Decision Maker (SDM)" regarding eating and drinking?

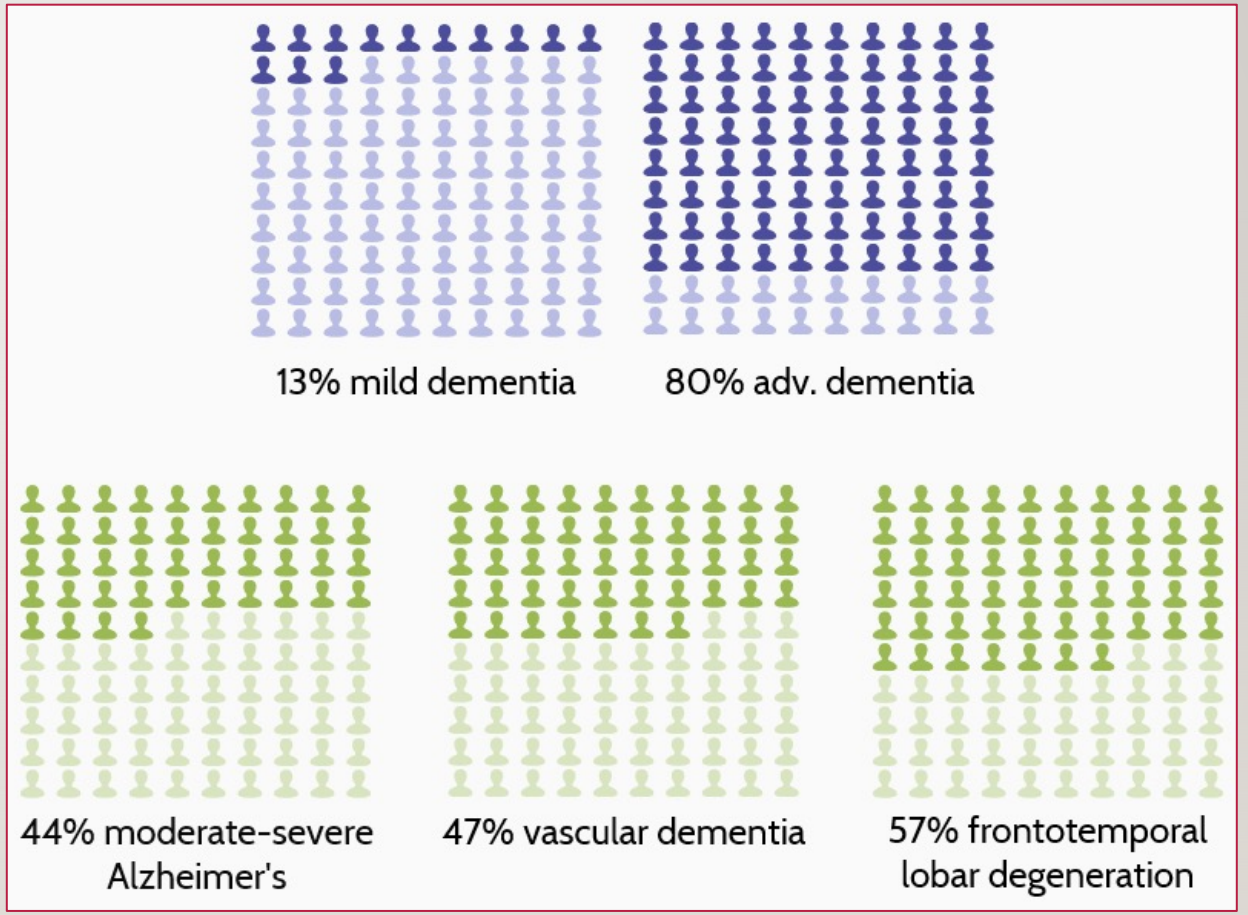
1) Is the Patient/SDM and medical team aligned on goals regarding ingestion of foods/liquids? Clarify the understanding of the goal. *Specifically, where are they on these continuum?*

PROBLEM AND RELEVANCE

- 70% of LTC residents have dysphagia (eating and swallowing difficulties)
- Dysphagia interferes with safety and comfort for eating/drinking and poses *medical consequences*. (Emergency Department and Hospital admissions)
  - Malnutrition, Dehydration, Aspiration pneumonia, Asphyxiation.
- **Therapeutic interventions have their own up/down side or risks/benefits**
  - Physical or emotional discomfort ↷ Pain
  - Deprivation of normalcy for mealtime.
  - Loss of pleasure and comfort for eating and drinking (socio-cultural)
- Sufficient evidence **LTC residents have poorer Oral Health***.

*. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4501060/

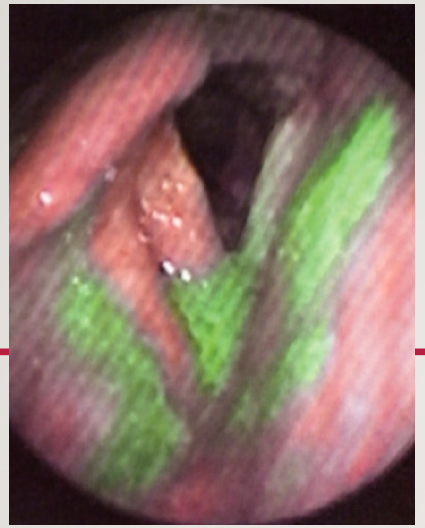




(Alagiakrishnan, Bhanjib, & Kuriansc, 2013; Hanson, Ersek, Lin, & Carey, 2013; Park et al., 2013; Sato et al., 2014)

INCIDENCE & COSTS FOR HOSPITAL ADMISSIONS FOR ASPIRATION PNEUMONIA - 5 YEARS 2011-2015

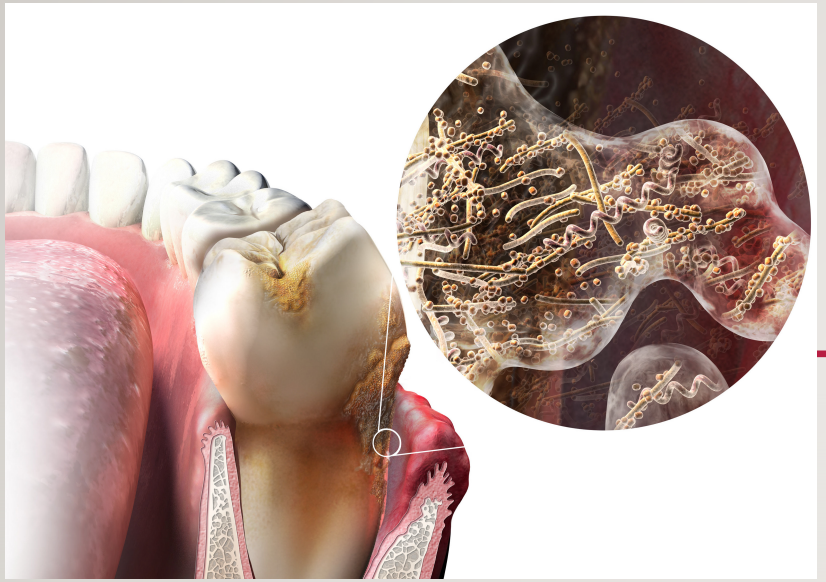
- **172 LTC Residents = $1.9 million**
- **78 PCH Residents = $1.8 million**
- **149 Other Institutions = $61.7 million**
- **399 incidences Total = $65.4 million**
- **+65 > (64% total)**
- **Men > Women (58% men)**

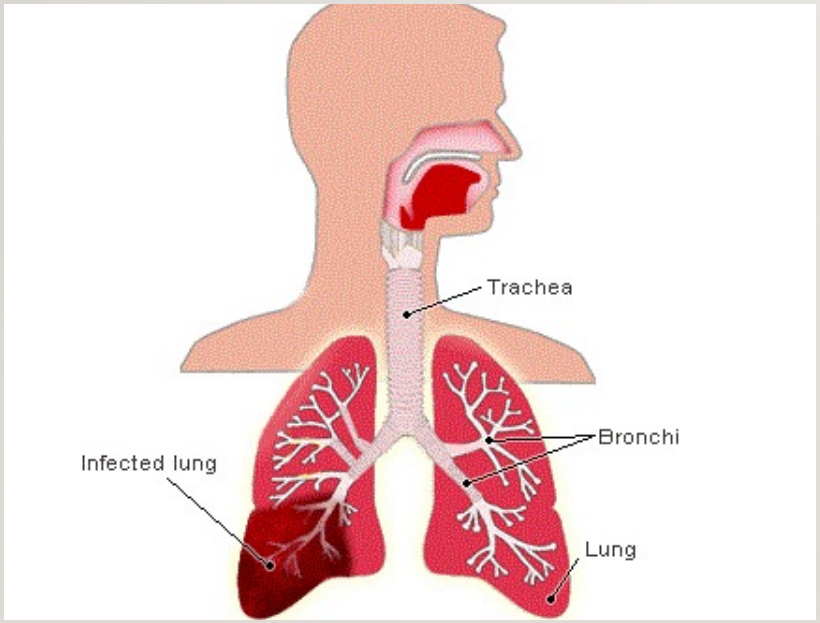


WHO IS MOST AT RISK TO DEVELOP ASPIRATION PNEUMONIA?

- Poor health status
  - multiple comorbidities (stroke, COPD, cardiovascular)
  - polypharmacy
  - poor nutritional status
  - mobility (mobility helps to clear secretions from lungs)
- Oral-pharyngeal dysphagia
  - Greater risk of chronic/silent aspiration
- **Poor oral health**
  - tooth decay and gum disease
  - rely on others for oral care

(Janssens, 2005; Kikawada, Iwamoto, & Takasaki, 2005; LANGMORE, SKARUPSKI, PARK, & FRIES, 2002; Langmore et al., 1998; Ortega et al., 2015; van der Maarel-Wierink, Vanobbergen, Bronkhorst, Schols, & de Baat, 2011)

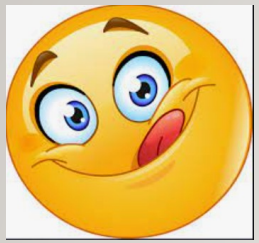


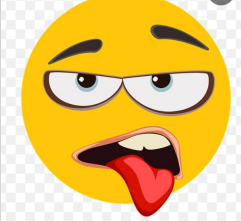


WHAT IS THE CONNECTION BETWEEN DYSPHAGIA AND ORAL HEALTH ISSUES?

- *The mechanism for how aspiration contributes to pneumonia
- Build up of **bacteria in mouth**
- **Pathogens carried to lungs** in aspirated secretions, fluids, or food

(Pace & McCullough, 2010; Scannapieco, 1999; Sumi, Miura, Michiwaki, Nagaosa, & Nagaya, 2007; image from http://www.medicalook.com/Lung_diseases/Aspiration_pneumonia.html)





INTERVENTIONS HAVE THEIR OWN - RISK/BENEFIT RATIO

- Intervention: **Thickening liquids to reduce episodes and amount of aspiration**
- Upside or Benefit: Makes drinking safer, more comfortable, and promotes hydration
- Downside or Risk: The YUCK Factor! Refusal of thick liquids- dehydration
- Is there an *alternative* we can recommend as choice?
- Frazier Free Water Protocol FFWP (Modified),
  - Effective in rehabilitation setting.
  - Allows for thin water between meals in a 'clean' mouth – *Requires oral hygiene*.

Free Water Protocol not studied in older adult residents with dementia in LTC facility.

RELATED RESEARCH QUESTIONS

1) For an older adult population with neuro-cognitive decline, is there a way to provide *alternative* recommendations to keep them '*safer*', but that has less impact on their enjoyment at mealtime? FEASIBLE and PRACTICAL?

- Modified *FFWP* intervention v. *Sham* intervention "Friendly visit" as the control.
- RCT to compare the intervention to the control groups.
- Outcomes (quantitative analysis on health measures):
  - ✓ Intervention group has better health outcomes than control group
  - ✓ No differences between the intervention/control groups on health outcomes
  - X Control group has better health outcomes than intervention group

RELATED RESEARCH QUESTIONS

2) Would the required extra tooth-brushing for the FFWP and the dental hygienist assessment and cleaning be tolerated by older adults with neuro-cognitive declines?

NOT DETRACT FROM QUALITY OF LIFE? DISTRESSING?

- Outcomes (quantitative analysis on dosage/tolerance):
  - ✓ Intervention group has higher dosage and better tolerance than control group
  - ✓ No differences between the intervention/control groups on dosage/tolerance
  - X Control group has higher dosage and better tolerance than intervention group

RELATED RESEARCH QUESTIONS

3) How do the stakeholders within the LTC facility (i.e., substitute decision makers, family, nursing staff, allied health professionals) rate the study (i.e., for understanding the potential role of enhanced oral hygiene care and minimizing the restriction of thin fluids).

INFORMED AND VIEWED BY STAFF AS POSITIVE?

- Outcomes (qualitatively assessed via survey):
  - ✓ Positively increased their knowledge and *positive* influence on the care of the residents.
  - ✓ No increase to their knowledge and was *neutral* influence on the care of the residents.
  - X The study was a burden/distressing and *negative* influence on the care of the residents.

NL-SUPPORT FOR *PEOPLE & PATIENT* ORIENTED RESEARCH & TRIALS - GETTING ALIGNMENT

- Patient engagement – what's important to them
- Patient-family centered – People as a family unit
- Clinician driven – Those in the trenches, the pressing issues to be studied
- Stakeholder alignment (researcher, clinicians, patients, families, institutions).
- Our Team

NL-SUPPORT FACILITATED THE CREATION OF OUR TEAM

REQUIRED STAKEHOLDERS

- Researcher(s) Co-Principal Investigators
  - Clinicians and Researchers
- Institutional approvals

OUR STAKEHOLDERS

- Cindy Holden and Roberta DiDonato
- Registered as Clinical trial
- Health Research Ethics Board
- Research Proposal Approvals Committee (RPAC)
- Site approvals
  - Eastern Health
  - Pleasant View Towers
  - Nursing management (multiple levels)

NL-SUPPORT FACILITATED THE CREATION OF OUR TEAM

REQUIRED STAKEHOLDER

- Patient representative
- Family representative
- Clinician(s): Interdisciplinary Healthcare
  - Many healthcare clinicians who would inform the study and play an active role in recruiting and conducting the study.

OUR STAKEHOLDERS

- A LTC resident with Parkinson who was an active member of the resident committee
- *Daughter-in-law of a LTC resident (not in the study).

NL-SPOR FACILITATED THE CREATION OF OUR TEAM

REQUIRED STAKEHOLDER

- Clinician(s)

OUR KEY STAKEHOLDERS

- Registered Speech-Language Pathologist (3)
- Registered Dental Hygienist (2)
- Resident Care Manager (2)
- Registered Nurse (2)
- Nurse Practitioner (2)
- Registered Dietician (1)
- Nursing Student (1)
- Research Assistant (1)

CHAMPIONS FOR DEALING WITH THE REALITIES

OUR CHAMPIONS

- **Alison Craggs, RCM;**
- Leanne Simmons, RCM
- Vicki Doyle, NP
- Sarah Coffin, Student nurse
- Melissa Layman, undergraduate research assistant
- Lori Greene, Christina Hodder, Irene Doody, SLPs
- Trudi Mead, RD
- RNs, LPNs, and Personal Care Attendants

"WHEN RESEARCH GOES OFF THE RAILS"

DESIGN AND METHOD: "RIGOR AND REALITY"

APPROVALS

- NIH clinical trial registration: Sept. 2018
- HREA approval: Oct. 2018
- Research Proposal Approval Committee (RPAC): **June 2019**

DELAYS IN STUDY INITIATION

- Change in lead position within RPAC
- Change in lead position within PVT
- Nursing staffing crisis in EH

Do You Have Trouble Swallowing And Want to Improve Your Fluid Intake?

Would you like to take part in a research study?
We are looking for patient partners in long term care who currently

- Have some difficulty swallowing
- Have been restricted to drinking only thicker liquids
- Complain that they feel thirsty or that their mouth is dry

You may be eligible to participate in a research study examining a liquid water protocol with oral hygiene care.

Please Contact….Researcher, HREA etc.

PROPOSED METHOD

- **Recruit convenience sample of 36** residents randomly assigned to intervention and control groups (18 in each);
- All would receive **swallow assessment** and **oral health assessment** at the start;
- Intervention group would receive **oral debridement by RDH** at the start of study period; control would receive same at the end;
- **Nursing staff would be trained with oral care for this population**;
- Study period for both groups **for 3 continuous months;**
- **Survey of all** participants, and staff regarding experience with the study.

INCLUSION/EXCLUSION

- Residents with moderate-severe dysphagia;
- Neurocognitive degeneration;
- Consent form incorporated EH Policies 050 and 140;
- No active respiratory disease, or pain presumed to be oral in nature;
- No responsive behaviours that would interfere with participation in the study.

INTERVENTION/CONTROL

INTERVENTION GROUP

- Receives standard nursing oral care and continued current diet;
- Receives dental hygiene debridement at **beginning** of study period;
- Intervention: FFWP with tooth brushing between mealtimes throughout study period.

CONTROL GROUP

- Receives standard nursing oral care and continued current diet;
- Receives dental hygiene debridement at **end** of study period.
- No intervention – Sham intervention
  - "Friendly visit"

CHANGES IN STAFFING & MODIFIED METHODS

- Registered Dental Hygienist (RDH)
- Gentle Persuasion Approach training
- FFWP- modified to 5 days M-F only twice daily mid-morning and afternoons
- Additional (non-staff) assistance
  - Nursing student- NUTRA Grant
  - Research Assistant

Keys and Legends

Tolerance to "Thin" Water	Proceed?	Rating/Data codes
Excessive coughing/unable to continue:	No	"0"
Moderate cough/clearing throughout session:	No	"1"
Mild coughing /clearing throughout session:	Maybe*	"2"
Throat clearing/wet vocal quality intermittently:	Yes	"3"
No coughing or change in voice:	Yes	"4"
No overt symptms noted:	Yes	"5"
* discontinue if distressed or wishes to stop		

Unable to schedule, initiate or complete Toothbrushing/provide water/friendly visit	Data Codes
Infectious with protective mask/gloves/gown required:	"10"
Medical Test Scheduled/transported off site:	"11"
Generally unwell:	"12"
Fluid restriction/NPO for any reason:	"13"
Agitated or combative:	"14"
Level of alertness is inadequate to initiate or complete	"15"
Do NOT Proceed.	

Tolerance to Tooth Brushing	Rating/Data Code
full refusal	0
Initially receptive but less than 1 quadrant comple	1
1 quadrant completed	2
2 quadrants completed	3
3 quadrants completed	4
all 4 quadrants completed	5

Tolerance to Friendly Visit	Rating/Data Code
Full refusal	0
Initially receptive but less than 1 minute	1
1-2 minutes visit with some engagement	2
3 minute visit with some engagement	3
4 minute visit with some engagement	4
Full 5 minute visit with some engagement	5

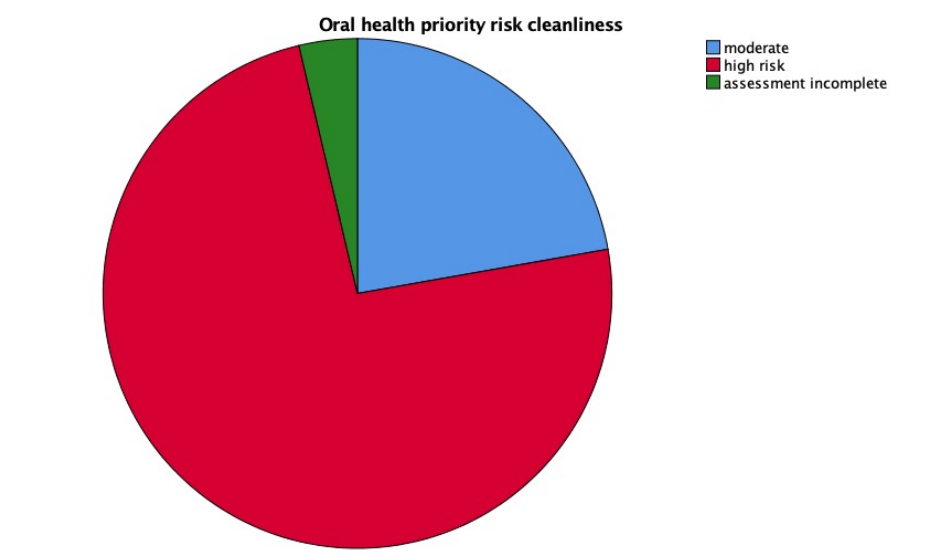
SUPPLIES AND EQUIPMENT

RESULTS - PARTICIPANTS

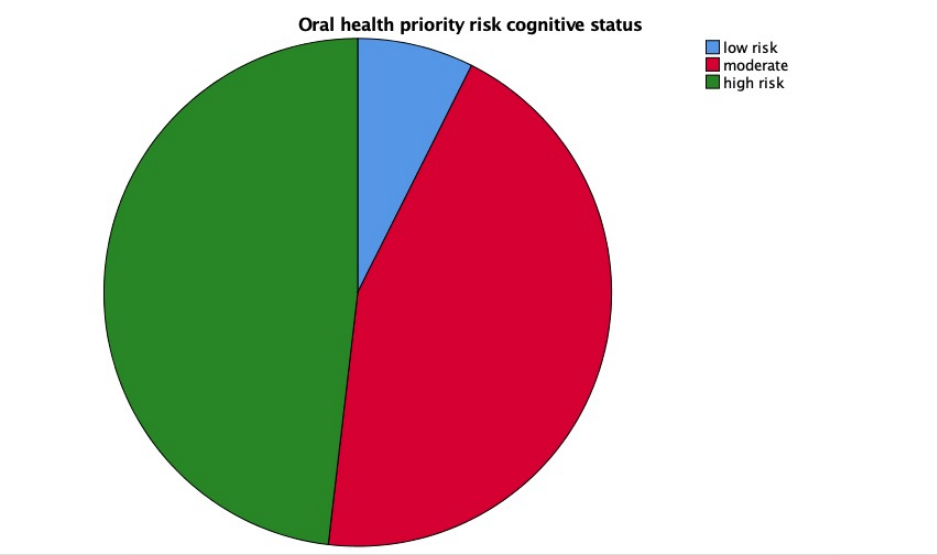
- N = 27 Exp. N = 13 (4-males), Control N =14, (4-males)
- Well-matched groups on Demographics
- Sex – 70% women,
- Age: Mean age = 83 years, Range: 67-101 (Exp = 83 years; Control = 82 years)
- Well-matched at Baseline (analyzed with parametric/nonparametric)
- Oral Health Risk factors
- SLP Assessment, 82% Moderate dysphagia 74% diet modified
- Health outcomes: Nutrition & Hydration; Symptoms (Sxs) of Chest infections

RESULTS - PARTICIPANTS

CLEANLINESS - 96% POOR

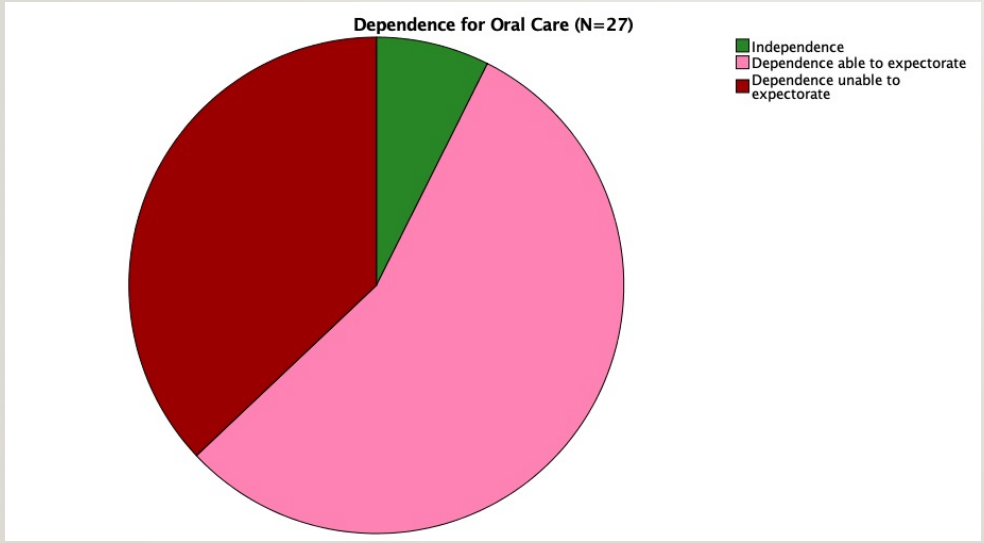


COGNITIVE STATUS - 92% IMPAIRED

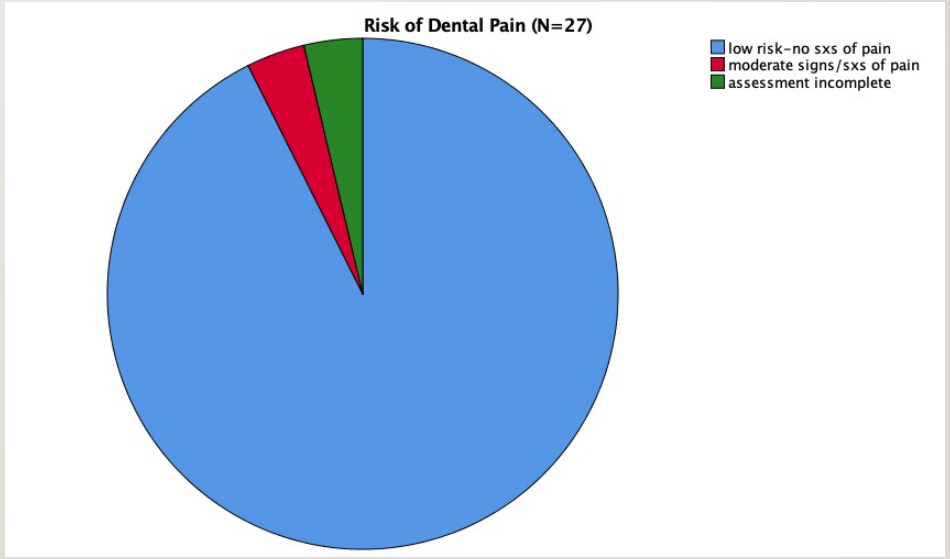


RESULTS - PARTICIPANTS

DEPENDENCE FOR ORAL CARE- 93%

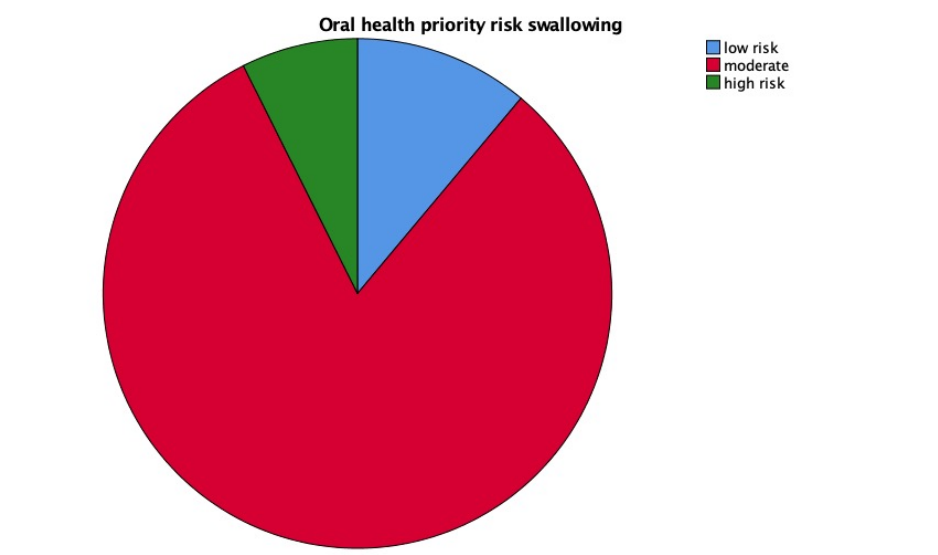


RISK OF DENTAL PAIN – 8%

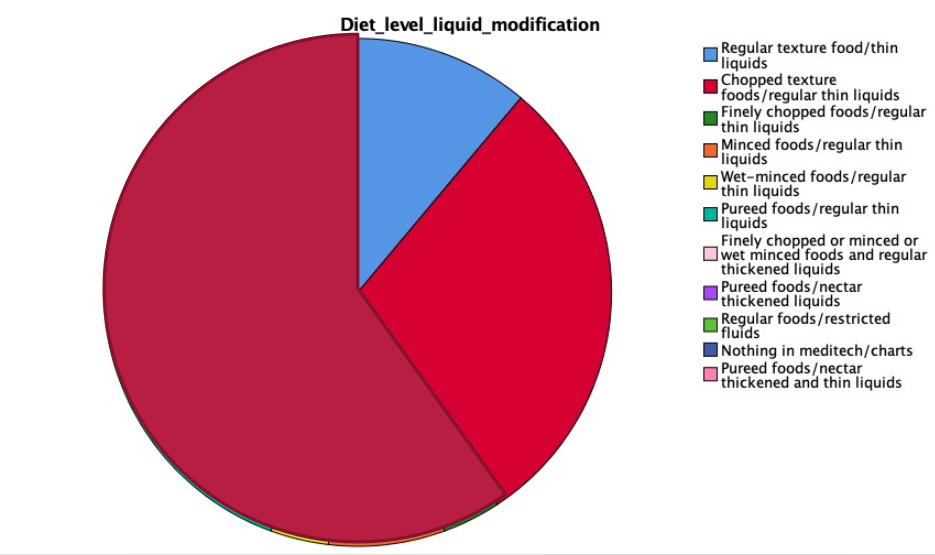


RESULTS - PARTICIPANTS

SWALLOWING RISKS 89%



DIET TEXTURE MODIFICATION 85%



HEALTH OUTCOMES: LABS PRE AND POST

Health Outcomes at Baseline (Pre) and Final (Post) (N=26)

	N	Range	Minimum	Maximum	Mean	Std. Deviation
Health outcome-Pre Hydration	26	161	44	205	88.92	36.000
Health outcome-Post Hydration	23	273	46	319	89.13	58.068
Health Outcome-Pre-Nutrition	23	.26	.13	.39	.2383	.05959
Health Outcome-Post_nutrition	16	.20	.14	.34	.2475	.05447
Valid N (listwise)	14					

RESULTS – OH ASSESSMENTS AND DEBRIDEMENT TOLERANCE

- Oral Health Assessment was well tolerated and completed 67% with mostly or perfect compliance, 15% refused or had incomplete assessments, 18% re-approach.
- RDH Debridement was *fairly* well tolerated and completed 56% with mostly or perfect compliance, 15% refused or had incomplete assessments 18% re-approach.
- No difference between groups for tolerance to Oral health Assessment or RDH debridement
- Study participation: time duration ranged between 2-30 days; dosage 2-36 episodes; successfully provided intervention 76% of attempts.

RESULTS - RESEARCH QUESTIONS

1) FFWP VS. FRIENDLY VISIT

- No difference between groups
  - Health outcomes
  - Few reported symptoms of chest infections
  - No aspiration pneumonia events
  - No hospital admissions

2) DOSAGE & TOLERANCE

- Difference for % of successful interventions: Friendly > FFWP
- No difference in Dosage (15 vs. 19)
- No difference in rated tolerance to sessions: Overall 78% tolerated sessions.

RESULTS - RESEARCH QUESTIONS

3) SURVEYS/RATING THE STUDY

- Too few completed surveys
  - Anecdotal support for study
  - LPNs and PCAs appreciate and engaged in study
  - Family expressed support and appreciation
  - Allied health staff-championed the study

LIMITATIONS AND FUTURE STUDY?

- With GPA® training, the research student nurse provided the extra tooth brushing and water.
- No evidence of harm done during this study.
- No evidence of health benefit found during this study.

CONCLUSION CONSIDERING THE 4-ETHICAL PILLARS:

- Extra oral hygiene care facilitated by a nursing staff with a child-sized soft toothbrush was well-tolerated in older adults with neuro-cognitive decline.
- The Registered Dental Hygienist (RDH)'s oral assessment and debridement of accumulations and biofilm can be effectively managed in the patient's own residence, **fairly tolerated**.
- It was *feasible* to implement and study the FFWP with this cohort, well tolerated, and no more distressing than a 'friendly' visitor.
- The study informs clinicians in best practice for *promoting quality of life* and offers *choice* to patients and their families *without causing harm*.
- *Justice*, a study to determine FFWP candidacy in a highly vulnerable patient cohort provided some empirical support for interventions that promote pleasure/comfort for mealtime at end of life.