Malnutrition, Dysphagia and Tongue Strength in Long Term Care

by

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A thesis submitted in conformity with the requirements for the degree of Doctor of Philosophy
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This dissertation investigated the relationships between malnutrition, dysphagia, tongue strength and mealtime outcomes in elderly residents of long term care (LTC) in three phases: a systematic literature review, prospective collection of data in LTC, and a tongue strengthening intervention. The primary goals were to determine: the prevalence of malnutrition and dysphagia; whether signs of dysphagia and reductions of tongue strength impacted meal consumption, and thereby contributed to malnutrition; and the feasibility of conducting a tongue strengthening intervention to improve mealtime outcomes. The systematic review (Chapter 2) revealed imprecise prevalence estimates for malnutrition and dysphagia due to varying definitions and measures across studies. Pilot data were collected (Chapter 3) to demonstrate the feasibility of collecting tongue strength, dysphagia and mealtime outcome data in this setting. Based on the success of the pilot study, a larger study was conducted with a sample comprising residents from 32 LTC homes (Chapter 4). Through this study, we found evidence of relationships between reduced swallowing pressures and dysphagia, as well as dysphagia and malnutrition. Finally, a tongue strengthening intervention was trialed in LTC, with the goal of improving mealtime outcomes (Chapter 5). The findings of this dissertation make several
unique contributions to the dysphagia literature. This dissertation has established that dysphagia and malnutrition co-exist in LTC, and that the odds of malnutrition are increased in the presence of signs of dysphagia. Further, it has demonstrated that reduced swallowing pressures and longer mealtimes are closely linked to signs of dysphagia, and that suspected dysphagia increases almost four-fold in the context of reduced swallowing pressures. This research has shown that tongue strength can be improved in people living in long term care and, these data have contributed the first set of reference values for tongue strength of residents of LTC. Limitations are acknowledged and future work is suggested. [300 words]
Acknowledgements

As I reflect on my doctoral studies, it is hard to believe that this chapter of my scientific journey is coming to an end. However, the end of one chapter signifies the beginning of another. So while I am saddened to end this chapter, I am also excited for all of the opportunities that await. None of those opportunities would be possible without two things: the hard work and dedication that has carried me here and the people who were instrumental in making this achievement a reality.

First, I must acknowledge someone who I am honoured and proud to call a supervisor, mentor, colleague and, most importantly, my friend, Dr. Catriona Steele. Catriona, you have taught me how to be a researcher, the importance of robust scientific discovery, and how to always keep my patients at the forefront of my research. Thank you for being a model clinician, researcher, educator, mentor and professional. Thank you for being one of my biggest supporters through both the academic and personal ups and downs of this journey, for sharing your network with me, and making sure that I have been poised in every opportunity that has come my way. I could not have asked for a better doctoral supervisor so thank you for believing in me even before I knew this was the right path for me. Thank you for being so generous with your time; your commitment and dedication to your students and the lab is truly inspirational. All that I have learned would not have been possible without your support and guidance, and I will be forever grateful.

To Dr. Heather Keller, who has mentored me through this work, thank you for including me in the Making the Most of Mealtimes project. Your ability to see a gap in knowledge, take initiative in understanding the problem of malnutrition in long term care, and then working to create viable solutions has been inspiring. Thank you for allowing me to come along for the ride.

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like to recognize the support of the Toronto Rehabilitation Institute, University Health Network and the Department of Speech-Language Pathology at the University of Toronto for their support over the past few years. Further, I would like to acknowledge the long term care residents who participated in my studies.

And finally, I would like to thank my family and friends who have been my rocks; your collective love and support has been palpable. To my sister, Keshini, thank you for keeping me grounded and for constantly reminding me of what really matters in life. To my parents, Shyami and Nama, thank you for never doubting my abilities and supporting me through 11.5 years of post-secondary education. Thank you for helping me keep the end goal in focus, and providing an endless number of distractions in the form of dinners and vacations around the globe that have allowed me to recharge. You have ignited this passion for knowledge within me through your constant encouragement to learn and grow, and I hope to make you both proud. Lastly, but certainly not least, to my husband and very best friend, Kyle, thank you for your unwavering love and patience. Thank you for graciously accepting the brunt of my stress, and for providing delicious lunches, clean laundry, a stocked fridge and a clean apartment when I could not lift my head up from my work. Thank you for being my sounding board throughout this journey. You have truly been my number one cheerleader and supporter.
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Chapter 1
Introduction and Thesis Overview

Introduction

Malnutrition, defined as an inadequacy or imbalance in energy and/or nutrients to meet the body’s functional needs (Soeters et al., 2008), occurs in more than half of residents living in long term care (LTC) (i.e., residences where two or more hours per day of nursing care are provided, also called nursing homes) (e.g., (Allard et al., 2004; Boström, Van Soest, Kolewaski, Milke, & Estabrooks, 2011; Bourdel-Marchasson, Helmer, Fagot-Campagna, Dehail, & Joseph, 2007; Carrier, Ouellet, & West, 2007; Jesus et al., 2012; Kuikka et al., 2009; López-Contreras, Torralba, Zamora, & Pérez-Llamas, 2012; Sitter & Lengyel, 2011)). Consequences of LTC malnutrition include: infections; falls; pressure ulcers; declines in function and cognition; hospital admissions; extended lengths of stay in hospital; and death (e.g., (Amaral et al., 2010; Arvanitakis et al., 2008; Donini, De Felice, & Cannella, 2007; Zuliani et al., 2001)). These outcomes are costly to the system, both in terms of health care and patient flow. LTC residents are a relatively small proportion of the 65 and over age group, yet they account for approximately 10% of all acute care admissions in Canada (Jennifer, Gary, David, Steven, & Colleen, 2009). When residents return to their LTC home after hospitalization they are often more confused and functionally impaired. Poor food and fluid intake is the primary cause for LTC malnutrition; average consumption has been estimated at 50% of food offered (Wendland, Greenwood, Weinberg, & Young, 2003). LTC malnutrition is both preventable and treatable. Interventions that promote food consumption are also likely to improve the health and function of residents.

As age increases, the risk of dysphagia, or swallowing impairment, also increases. Swallowing involves a series of three phases: oral, pharyngeal, and esophageal. Each of these phases requires several muscles and nerves to be intact in order to facilitate a safe and efficient swallow. Dysphagia occurs when any of the muscles or nerves involved in swallowing are damaged or become weak and involves two primary functional concerns: a) penetration-aspiration (when material enters the airway); and b) residue, which is left behind in the spaces of the pharynx, and can cause post-swallow aspiration. Dysphagia is common in individuals with
neurological diagnoses (stroke (Perlman, 1996; Shaker & Geenen, 2011), brain injury (Avery-Smith & Dellarosa, 1994; Field & Weiss, 1989), Parkinson’s disease (Leopold & Kagel, 1997; Robbins, Logemann, & Kirshner, 1986), etc.) or following head and neck cancer (Eisbruch et al., 2004; Pauloski et al., 2002). Dysphagia is also a known comorbidity of dementia (Easterling & Robbins, 2008). According to the Alzheimer’s Society of Canada (Alzheimer’s Society, 2012), approximately 747,000 Canadians currently have some type of dementia and more than 200,000 of these people reside in LTC. When present, dysphagia predisposes individuals with dementia to dehydration, malnutrition, weight loss, and aspiration pneumonia (Hudson, Daubert, & Mills, 2000; Mendez, Friedman, & Castell, 1991; Mion, McDowell, & Heaney, 1994). Medical recovery can also be negatively impacted by dysphagia, which often causes longer hospitalization and an increased need for LTC (Odderson, Keaton, & McKenna, 1995).

There are also some physiological changes in swallowing that are reported to occur as part of healthy aging (presbyphagia). In general, the elderly are reported to have slower and more variable movements (Christou & Carlton, 2001; Karlsson & Carlsson, 1990), decreased amplitude of movement with increased variability (Lexell & Downham, 1992) and increased latency of response to sensory stimuli (Bugnariu & Sveistrup, 2006). Much of this research has been done on the limb musculature, but studies suggest that the orofacial motor system is similarly affected. One study performed by Bennett and colleagues reported that older adults have slower and more variable tongue movements during swallowing (Bennett, van Lieshout, & Steele, 2007). Other studies have also pointed to age-related diminishment in strength, mobility and endurance of the tongue (Nicosia et al., 2000; Robbins, Levine, Wood, Roecker, & Luschei, 1995). Tongue strength is essential for the oral and pharyngeal phases of swallowing. The tongue contributes to the formation, placement, and manipulation of the bolus within the oral cavity, and its propulsion into the pharynx (Youmans & Stierwalt, 2006). Weakness in any of the eight muscles of the tongue may contribute to difficulties with bolus control and ineffective bolus propulsion. The implications of tongue weakness and dysphagia in LTC need to be better understood, especially with regard to those who are in LTC and at risk for malnutrition.

Regardless of pathophysiology, swallowing impairments place a person at risk of reduced nutritional intake (Altman, Yu, & Schaefer, 2010; Sura, Madhavan, Carnaby, & Crary, 2012; Wright, Cotter, Hickson, & Frost, 2005). Given that both aging and dementia increase the risk of having dysphagia, and that dysphagia can lead to malnutrition, it is logical to explore the
associations between these conditions. Due to the fact that self-feeding is not always adequately supported in LTC and eating assistance can be limited, residents with dysphagia may be particularly prone to inadequate food intake. Improving LTC food intake has been identified as a priority by researchers, decision makers and users to promote health and quality of life of residents. Yet, our understanding of why inadequate food intake occurs in LTC is fragmented. The overarching goal of this research was to determine whether dysphagia and tongue strength play a contributory role to malnutrition of adults in LTC. If signs of dysphagia and reductions in tongue strength can be demonstrated to be impacting meal consumption, and thereby contributing to malnutrition, we may be able to develop interventions to mitigate this problem. The purpose of this dissertation is to explore the relationships between tongue weakness, dysphagia, malnutrition and food intake for elderly residents in LTC.

**Thesis Overview**

This dissertation begins with a systematic review summarizing the literature with respect to the co-occurrence of malnutrition and dysphagia in elderly residents of LTC (Chapter 2). Our goal was to better understand how malnutrition and dysphagia are typically described and measured in LTC, and to determine how often the two conditions occurred simultaneously. The lack of standard definitions and measures to measure both malnutrition and dysphagia highlighted gaps in our understanding of the prevalence of each condition on its own, but also how they might impact each other.

The results of the systematic review inspired me to collect information pertaining to dysphagia and food intake in a small pilot study (12 LTC residents; 5 male), in a more robust way than what has previously been reported. The goal was to explore the feasibility of conducting such an experiment in the LTC setting, but also to see whether tongue strength might be impacting functional mealtime outcomes (Chapter 3). This study was conducted as a part of the M3 (Making the Most of Mealtimes) project, for which the principal investigator is Dr. Heather Keller at the University of Waterloo. The documents pertaining to Research Ethics Board (REB) approval of the collection of these data appear in Appendix A and post-hoc analyses of significant effects were further explored using Cohen’s $d$ found in Appendix B. From this study we learned that measuring tongue strength, screening for dysphagia and measuring mealtime outcomes were feasible in LTC.
Based on the results of the small pilot study, we then continued on to conduct a similar study on a much larger scale. The M3 study collected data regarding nutrition and factors contributing to malnutrition from 32 LTC homes across Canada. There were 8 homes in each of the following provinces: Alberta, Manitoba, Ontario and New Brunswick. A total of 639 elderly residents were assessed for malnutrition, signs of dysphagia and mealtime outcomes. A subset of residents in Ontario also underwent tongue strength assessment. The goal of the study was to further elucidate the relationships between malnutrition, dysphagia, tongue strength and mealtime outcomes. The documents pertaining to REB approval of the collection of these data appear in Appendix A. The analyses in Chapter 4 document these relationships.

In one of the final chapters (Chapter 5), I developed and trialed a tongue strengthening intervention in a small group of LTC residents, as a proof-of-principle study. The documents pertaining to REB approval of the collection of these data appear in Appendix A. In routine practice, residents of LTC do not receive swallowing therapy; their diets are modified if swallowing impairments are identified. My goal in Chapter 5 was to determine if a tongue strengthening therapy was feasible, and whether it would have positive effects on functional mealtime outcomes.

The dissertation closes with a chapter summarizing the major contributions from the studies contained within and considers implications for future research (Chapter 6). Three chapters are verbatim excerpts from either published manuscripts (Chapter 2 and 3) or submitted manuscripts (Chapter 5). Therefore, the reader is advised that this dissertation may contain redundant information across chapters. The reader should also note that the referencing-style of each chapter is consistent with the requirements of the journal in which the chapter is published/submitted.
References


Bennett, J. W., van Lieshout, P. H. H. M., & Steele, C. M. (2007). Tongue Control for Speech and Swallowing in Healthy Younger and Older Adults.


Chapter 2
Malnutrition and dysphagia in long term care:
A systematic review

With kind permission from Taylor & Francis, this chapter was excerpted in its entirety from the following journal article: Namasivayam, A. M. & Steele, C.M. (2015). Malnutrition and dysphagia in long term care: A systematic review. Journal of Nutrition in Gerontology and Geriatrics. 34(1):1-21. This article can be found on the publisher’s website at: http://www.tandfonline.com/doi/abs/10.1080/21551197.2014.1002656.

Abstract
Background: Determining the co-occurrence of malnutrition and dysphagia is important to understand the extent to which swallowing impairment contributes to poor food intake in long term care.

Objective: To investigate the impact of dysphagia on malnutrition in long term care by synthesizing the results of published literature.

Methods: Studies were searched for using seven electronic databases for English-language publications from 1946 to November 2013.

Results: Fourteen studies were eligible for inclusion. Overall, the literature on the co-occurrence of malnutrition and dysphagia in LTC shows a paucity of high-quality evidence. The articles reviewed lacked consistent definitions for both malnutrition and dysphagia, with some articles failing to provide any explanation as to their use of these terms. Methods used to confirm each diagnosis also differed greatly and were of questionable validity.

Conclusions: Based on a careful review of the literature, evidence of the existence of concurrent concerns with respect to malnutrition and dysphagia emerges. However, due to discrepancies used to describe and measure these conditions, it is difficult to determine the prevalence of either condition separately, or in combination. For researchers and clinicians alike, the impact of dysphagia on malnutrition must be seriously considered.

Key words: Deglutition, dysphagia, malnutrition, long term care, nursing homes
Introduction
Adults over the age of 65 who live in long term care (LTC) facilities (including nursing homes, assisted living, and dementia care units), are considered to be nutritionally vulnerable. Malnutrition is estimated to be present in 30-60% of LTC residents, and has negative consequences for health, well-being and quality of life (1). Malnutrition is often the result of suboptimal food intake (2), and may also occur as a secondary consequence of acute or chronic disease (3) with an associated risk of micronutrient deficiencies (4-6). Malnutrition can also lead to hospitalization. Hospital admissions from LTC account for approximately 10% of all acute care hospital visits (7). Some of the associated healthcare costs might be avoidable if nutritional status were improved in LTC. However, in order to limit malnutrition and mitigate the associated costs, it is critical that the factors associated with and contributing to malnutrition in LTC are determined.

With age, many people are also at a heightened risk for swallowing impairment (dysphagia). Two primary functional concerns are seen in dysphagia: a) the entry of food or liquid material into the airway (aspiration); and/or b) the accumulation of residue in the throat after a swallow (8). Dysphagia may arise from age-related physiological changes, such as sarcopenia (muscle loss), and can contribute to malnutrition. Dysphagia is a frequent concern for those in LTC, with as many as 74% of residents having swallowing difficulties (9). There is an even higher prevalence of dysphagia among those with dementia (10). Due to the fact that self-feeding is not always adequately supported, and the limited availability of staff who can provide mealtime assistance (11), LTC residents with dysphagia may also experience limited food intake and may not receive the nutrients they require to thrive.

Despite the fact that malnutrition in LTC residents is a pressing issue, a systematic investigation into the relationship between dysphagia and malnutrition in the elderly has not yet been conducted. The analysis in this paper takes a first step in this direction by synthesizing the results of published literature on malnutrition and dysphagia in LTC. For the purposes of this review, broad definitions of the terms malnutrition and dysphagia were adopted to facilitate inclusion of a wide range of literature.
Methods
Search Strategy and Inclusion Criteria

A comprehensive literature search was carried out in November 2013 to find reports of either dysphagia and/or malnutrition in elderly individuals residing in LTC. The electronic retrieval systems and databases searched for relevant articles were PubMed (Medline), EMBASE, Cochrane Library, SpeechBITE, CINAHL, AgeLine, and AMED. The keywords (Medical Subject Headings in Medline) used were *deglutition, swallowing, eat* difficult*, drink* difficult*, malnutrition, nutrition disorders, dehydration, wasting syndrome, weight loss, undernutrition, long-term care, nursing homes, homes for the aged, housing for the elderly, skilled nursing facility*, assisted living, residential care, geriatric institution, and extended care facility. These terms were used isolation or in different combinations using Boolean operators. Terms were nominated by two speech-language pathologists and a librarian, and intended to capture terms and concepts known to be used in the dysphagia, nutrition and aging research communities to describe dysphagia and malnutrition in long term care.
Figure 1. A PRISMA Flow Diagram depicting the flow of information through the different phases of the systematic review, mapping out the number of records identified, included and excluded.

Records identified through database searching (n = 614)

Records after duplicates removed (n = 501)

Records after screening for English language and relevance (n = 399)

Records excluded (n = 92)

Records excluded, with reasons (n = 247)

Full-text articles assessed for eligibility via title and abstract (n = 307)

Studies included full text review of relevance, methods and quality (n = 60)

Studies included in synthesis (n = 14)
The search was limited to studies published in English from as early as 1946 in some databases to the present day. Figure 1 summarizes the yield of the literature search strategy according to the criteria laid out in the 2009 PRISMA guideline for systematic reviews (12). Before removing duplicates, the initial search yielded 614 publications. The removal of duplicates resulted in 501 articles to analyze further. These were reviewed to ensure that they were all English, peer-reviewed journal articles. Titles and abstracts were then screened for relevance with regard to describing participants residing in LTC facilities who had either malnutrition and/or dysphagia. Any articles that appeared to focus solely on participants who were being tube-fed, or who had esophageal or gastro-intestinal issues were excluded. Studies focusing on children were also excluded. Following this step in the screening process, 60 articles remained for further analysis. Full-text reviews were completed for all 60 articles, using a list of questions intended to confirm relevance (Table 1).

Table 1. *Criteria used for first phase of eligibility analysis.*

<table>
<thead>
<tr>
<th>Inclusion Criteria for screening of articles pertaining to both malnutrition and dysphagia in long term care</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Is the article from a peer-reviewed journal?</td>
</tr>
<tr>
<td>2. Does the article report measures of dysphagia?</td>
</tr>
<tr>
<td>3. Does the article report measures of malnutrition?</td>
</tr>
<tr>
<td>4. Does the article report on an elderly population (over the age of 65)?</td>
</tr>
<tr>
<td>5. Are the participants in the study living in LTC (i.e. nursing homes)?</td>
</tr>
</tbody>
</table>

Based on the questions in Table 1, the article set was narrowed down to a final inclusion list of only 14. Blinded duplicate rating was performed for n = 12 (i.e., 20%) of the full-text articles, resulting in perfect agreement between both raters regarding relevance and inclusion. The majority of excluded articles were eliminated because the authors discussed malnutrition and dysphagia but did not measure either of these conditions in any way. Nine articles were excluded because they focused on the elderly population living outside of LTC, either in acute care hospitals or within the community. Five articles were excluded because they did not discuss the elderly. Of the journal articles that were excluded, 16 did not discuss dysphagia and 15 did not discuss malnutrition.
Studies Included

Table 2. Questions posed to standardize analysis of final articles included in review.

<table>
<thead>
<tr>
<th>Questions used for final analysis of included articles</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. What was the objective of the study?</td>
</tr>
<tr>
<td>2. What was the author’s definition of malnutrition?</td>
</tr>
<tr>
<td>3. What was the author’s definition of dysphagia?</td>
</tr>
<tr>
<td>4. What was the measure used to determine malnutrition?</td>
</tr>
<tr>
<td>5. What was the measure used to determine dysphagia?</td>
</tr>
<tr>
<td>6. How many participants had dysphagia?</td>
</tr>
<tr>
<td>7. How many participants were malnourished?</td>
</tr>
<tr>
<td>8. How many participants were both malnourished and had dysphagia?</td>
</tr>
<tr>
<td>9. What conclusions did the authors draw from the study?</td>
</tr>
</tbody>
</table>

For the 14 articles selected for qualitative synthesis and data pooling, a review of study methods, results and quality was conducted using the questions in Table 2. The studies were then organized in two groups:

a) those reporting prevalence statistics in heterogeneous samples of LTC residents; and
b) those reporting the prevalence of dysphagia in restricted samples of LTC residents, enrolled on the basis of having malnutrition, or vice versa.

Risk of Bias

The evaluation for risk of bias was performed according to the guidelines suggested by the Cochrane Bias Methods Group (13). Specifically, each study was reviewed to determine whether there was potential bias in terms of participant selection, the detection or measurement of behaviors of interest, attrition or missing data, and reporting of results. As shown in Table 3, for the 14 studies reviewed, there identified risks with respect to bias for every single study. By far, the most common risk of bias lay in the failure to provide clear definitions of dysphagia and malnutrition. Another important risk of bias was the failure to report any information regarding the reliability of the measurements taken. Given that many of the measurements reported were
seemingly subjective, particularly when no clear definitions were provided and standardized assessment tools were not used, strong reliability is critical when assessing the results of the studies. Nonetheless, the literature reviewed lacked acknowledgement of this issue entirely. As such, caution is warranted in drawing generalized conclusions from this body of literature.

Table 3. Risk of bias evaluations

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Title</th>
<th>Risk of bias?</th>
<th>Type of bias</th>
</tr>
</thead>
<tbody>
<tr>
<td>Challa, Sharkey, Chen, &amp; Phillips</td>
<td>2007</td>
<td>Association of resident, facility, and geographic characteristics with chronic undernutrition in a nationally represented sample of older residents in U.S. nursing homes</td>
<td>+</td>
<td>Subjective assessment of “swallowing problems” through MDS; no information regarding reliability of ratings; data collected at various points post-admission for each participant</td>
</tr>
<tr>
<td>Flacker &amp; Kiely</td>
<td>1998</td>
<td>A practical approach to identifying mortality-related factors in established long-term care residents</td>
<td>+</td>
<td>Subjective assessment of “swallowing disorders” through MDS; no information regarding reliability of ratings</td>
</tr>
<tr>
<td>Flacker &amp; Kiely</td>
<td>2003</td>
<td>Mortality-related factors and 1-year survival in nursing resident</td>
<td>+</td>
<td>Subjective assessment of “swallowing disorders” through MDS; no information regarding reliability of ratings</td>
</tr>
<tr>
<td>Germain, Dufresne, &amp; Gray-Donald</td>
<td>2006</td>
<td>A novel dysphagia diet improves the nutrient intake of institutionalized elders</td>
<td>+</td>
<td>No information regarding reliability of ratings</td>
</tr>
<tr>
<td>Jürschik, Torres, Sola, Nuin, Botigue, &amp; Lavedan</td>
<td>2010</td>
<td>High rates of malnutrition in older adults receiving different levels of health care in Lleida, Catalonia: An assessment of contributory factors</td>
<td>+</td>
<td>Unclear definition of “difficulty swallowing” and unclear method of assessment; no information regarding reliability of ratings; different groups described in methods were pooled together in results; data for ten participants are missing and unexplained</td>
</tr>
<tr>
<td>Kumlien &amp; Axelsson</td>
<td>2002</td>
<td>Stroke patients in nursing homes: eating, feeding, nutrition and related care</td>
<td>+</td>
<td>Unclear definitions of “swallowing problems” and “nutritional problems” and no explanation of how these were assessed; no information regarding reliability of ratings</td>
</tr>
<tr>
<td>Leibovitz, Sharon-Guidetti, Segal, Blavat, Peller, &amp; Habot</td>
<td>2004</td>
<td>CD4 lymphocyte count and CD4/CD8 ratio in elderly long-term care patients with oropharyngeal dysphagia: Comparison between oral and tube enteral feeding</td>
<td>+</td>
<td>No information regarding reliability of ratings</td>
</tr>
<tr>
<td>Study</td>
<td>Year</td>
<td>Description</td>
<td>+/−</td>
<td>Notes</td>
</tr>
<tr>
<td>--------------------------------------------</td>
<td>------</td>
<td>-----------------------------------------------------------------------------</td>
<td>-----</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Leibovitz, Baumoehl, Lubart, Yaina, Platinovitz, &amp; Segal</td>
<td>2007</td>
<td>Dehydration among long-term care elderly patients with oropharyngeal dysphagia</td>
<td>+</td>
<td>No information regarding reliability of ratings</td>
</tr>
<tr>
<td>Leibovitz, Sela, Habot, Gavendo, Lansky, Avni, &amp; Segal</td>
<td>2002</td>
<td>Homocysteine blood level in long-term care residents with oropharyngeal dysphagia: Comparison of hand-oral and tube-ental-fed patients</td>
<td>+</td>
<td>No information regarding reliability of ratings</td>
</tr>
<tr>
<td>Leibovitz, Sela, Zlotnik, Baumohel, &amp; Segal</td>
<td>2005</td>
<td>Plasma levels of amino acids in elderly long term care residents with oropharyngeal dysphagia: Comparison of hand-oral with tube-ental-fed patients</td>
<td>+</td>
<td>No information regarding reliability of ratings</td>
</tr>
<tr>
<td>Morley &amp; Kraenzle</td>
<td>1994</td>
<td>Causes of weight loss in a community nursing home</td>
<td>+</td>
<td>Unclear definition of “swallowing disorder” and no explanation of how this was assessed; no information regarding reliability of ratings</td>
</tr>
<tr>
<td>Ramage, Ross, &amp; Hadden</td>
<td>1998</td>
<td>Assessing fluid intake of residents with oro-pharyngeal dysphagia</td>
<td>+</td>
<td>No explanation of how oropharyngeal dysphagia was assessed; no information regarding reliability of ratings</td>
</tr>
<tr>
<td>Suominen, Muurinen, Routasalo, Soini, Suur-Uski, Peiponen, Finne-Soveri, &amp; Pitkala</td>
<td>2005</td>
<td>Malnutrition and associated factors among aged residents in all nursing homes in Helsinki</td>
<td>+</td>
<td>Unclear definition of “difficulties swallowing” and no explanation of how this was assessed; no information regarding reliability of ratings</td>
</tr>
<tr>
<td>Tannen, Schutz, Smoliner, Dassen, &amp; Lannen</td>
<td>2011</td>
<td>Care problems and nursing interventions related to oral intake in German nursing homes and hospitals: A descriptive multicentre study</td>
<td>+</td>
<td>Unclear definition of “swallowing problems” and no explanation of how this was assessed; no information regarding reliability of ratings</td>
</tr>
</tbody>
</table>

**Results**

A brief overview of each study that met the final inclusion criteria is provided below. The studies are grouped according to those that had samples that were heterogeneous in nature versus studies that had samples that were more restricted.

**Heterogeneous sample studies**

Challa, Sharkey, Chen and Phillips (14) examined the relationship between chronic undernutrition and resident, facility, and geographical characteristics in a national sample of 128,514 nursing home residents aged 60 or older in the United States. This was a secondary analysis using data from the Minimum Data Set (MDS), for which malnutrition was assessed.
using the World Health Organization (WHO) criteria for undernutrition, defined as a body mass
index (BMI) of $<18.5\text{kg/m}^2$. A definition of swallowing impairment was not disclosed in the
manuscript, however, the operational definition of dysphagia on the MDS is the use of a texture
modified diet (15). The number of individuals who were found to be malnourished, to have
dysphagia and/or present with both conditions concurrently were reported as percentages of the
total sample.

Flacker and Kiely (16) sought to determine the factors associated with one-year
mortality in long term care residents. MDS records were examined and data regarding BMI and
the presence of a swallowing problem were extracted. Residents were divided into two
nutritional subgroups based on BMI: low ($\leq 22 \text{kg/m}^2$) or not low ($>22\text{kg/m}^2$). The authors also
explored weight loss as recorded on the MDS, where weight loss was defined as a loss of 5 or
more pounds in the previous 30 days or 10 or more pounds in the previous 180 days. An explicit
definition of swallowing problems was not provided. The percentages of individuals with
swallowing problems and weight loss were reported but frequency data were not provided for
the number of people with low BMI; rather, only the mean BMI for each nutritional subgroup
was reported.

In a later study, Flacker and Kiely (17) aimed to identify factors associated with one-
year mortality in newly admitted and long-stay nursing home residents by linking MDS
information with data from the National Death Index. Malnutrition and dysphagia were two of
the many factors assessed in 136,794 residents. Those who were malnourished were described
to have a “low” BMI ($\leq 23 \text{kg/m}^2$), and dysphagia was simply defined as “swallowing
problems,” with no mention of a standardized measure. Percentages of those with either a
swallowing problem or a low BMI were reported, but data regarding the co-occurrence of these
conditions was not provided.

The factors associated with the presence or risk of malnutrition in 398 older adults (>65
years of age) were studied by Jürschik (18) and colleagues. This sample included individuals
from different levels of care, including health centers, acute hospitals, social centers, and
nursing homes. The results of the study pooled all of these individuals together to make one
heterogeneous group, however, the results indicate that 24.3% of participants were recruited
from social health centers and 10.5% (i.e., approximately $n = 40$) participants were from
nursing homes. The authors used the Mini Nutritional Assessment (MNA) to assess nutritional
status (19). An undescribed questionnaire was used to capture data regarding swallowing problems and weight loss (defined as a history of weight loss $\geq 7\%$ in 3 months or $\geq 10\%$ in 6 months prior to assessment). The numbers and percentages of those noted to have weight loss, difficulty swallowing and to be in a poor nutritional state were reported.

Kumlien and Axelsson (20) studied eating, feeding and nutrition amongst 40 stroke patients in nursing homes. Malnutrition was measured by either a 5% weight loss over a 30-day period or a 10% weight loss over a 180-day period. Dysphagia, defined as not being able to swallow at all, having severe swallowing difficulties and/or a lot of coughing during mealtimes, was determined using the Resident Assessment Instrument (RAI) (21). The numbers of patients with a swallowing or nutrition problem were reported.

Morley and Kraenzle (22) studied the causes of weight loss in 156 nursing home residents. They classified those who were malnourished as those who had excessive weight loss (a loss of at least 5 pounds over 3 or more months). Dehydration was also determined by the presence of a blood urea nitrogen to creatinine ratio greater than 20:1. Nurses and dieticians were interviewed to determine whether study participants had a swallowing impairment. The numbers of participants with either or both conditions were reported.

Suominen and colleagues (23) collected information about nutritional problems and associated factors in all nursing homes in Helsinki, Finland. They assessed 2114 residents using the MNA (19), where malnutrition was defined as being present in those with less than 17 points on the assessment. How the authors determined whether the patients had difficulty swallowing is unclear and a definition of ‘difficulties in swallowing’ was not provided. The reported data include percentages of those who were deemed to be malnourished, to have dysphagia, and those found to have both conditions.

Tannen, Schutz, Smoliner, Dassen and Lahmann (24) reported on the prevalence of problems that potentially lead to decreased nutritional intake in 5521 people in German nursing homes. Patients with a BMI of $\leq 20$ kg/m$^2$ were classified as underweight and were therefore classified as being at risk for malnutrition. ‘Swallowing problems’ were assessed by observation and by questioning the patients using the Care Dependency Scale (25). No further details regarding the assessment of dysphagia were provided. The numbers of people with a swallowing and/or nutrition problem were reported by the authors.
Restricted sample studies

Germain, Dufresne and Gray-Donald (26) assessed swallowing in 27 frail institutionalized elderly persons considered to be malnourished. These authors deemed those with a BMI of < 24 kg/m$^2$ or weight loss > 7.5% within 3 months to be “frail”, or malnourished. In this study, dysphagia was defined as “difficulties eating or swallowing solids or liquids,” as determined by the Rehabilitation Institute of Chicago Clinical Evaluation of Dysphagia (27). From the baseline data provided, the number of participants who presented with both malnutrition and dysphagia can be extracted.

Leibovitz, Sela, Habot, Gavendo, Lansky, Avni and Segal (28) compared vitamin status and homocysteine blood levels in 26 cognitively impaired LTC patients with oral dysphagia. The Functional Outcome Swallowing Scale (FOSS) was used to classify dysphagia (29). All patients found to be at Stage 1 or 2 on the scale were included in the study. Those classified as Stage 1 have normal swallowing function with episodic or daily symptoms of dysphagia (29). At Stage 2, there is compensated abnormal function manifested by significant dietary modifications or prolonged mealtime (without weight loss or aspiration) (29). Fasting blood samples were obtained from all participants, and plasma homocysteine levels were subsequently measured by fluorescent detection. The blood samples were also used to measure serum folate, B$_{12}$ and B$_6$, while urine samples were analyzed for methylmalonic acid. Normal laboratory values and the study group mean values for each laboratory test were reported.

In a later study, Leibovitz, Sharon-Guidetti, Segal, Blavat, Peller & Habot (30) compared CD4 lymphocyte count and CD4/CD8 ratio between 28 orally fed people with dysphagia and 17 people using an enteral feeding tube. Each orally fed participant was assessed with the FOSS and included if they were at Stage 2. Given that the immunological status of the elderly is sensitive to undernutrition and that impaired nutritional status correlates with low CD4 lymphocyte count, the authors chose to measure the parameters of interest using blood samples. From the data provided, the numbers of study participants suffering from both malnutrition and dysphagia can be extracted. Subsequently, Leibovitz, Sela and Segal also co-authored a further study with Zlotnik and Baumohel (31). This study evaluated plasma amino acid levels through blood samples in 15 orally fed elderly patients with dysphagia. As in the previous studies from this group, all participants had Stage 2 swallowing difficulties on the FOSS. However, although
plasma amino acid levels were described, the number of participants with inadequate levels was not reported.

In a fourth study, Leibovitz, Baumoehl, Lubart, Yaina, Platinovitz and Segal (32) assessed hydration status in 95 elderly LTC residents with oropharyngeal dysphagia, of whom 28 were being fed orally. Dehydration, “a term used to reflect several physiological states based on the imbalance between intake and loss of fluid and the accompanying sodium status” was measured using urine and blood samples. The results were considered to be indicative of dehydration if they met the following criteria: blood urea nitrogen (BUN) above normal values (> 20 mg/dl); BUN/serum creatine (S_{Cr}) ratio > 20; blood sodium (S_{Na}) > 145 mEq/l; blood osmolality (S_{Osm}) > 295 mosm/kg; urine sodium (U_{Na}) < 10 mEq/l; urine osmolality (U_{Osm}) > 500 mosm/kg; urine/S_{Cr} ratio > 40, or urine/S_{Osm} ratio > 1.2. Dysphagia was again established using the FOSS, and all participants had Stage 2 scores on this scale. The reported results include frequency counts of the number of residents with both dysphagia and malnutrition.

Finally, Ramage, Ross and Hadden (33) wanted to determine the oral fluid intake of 29 oropharyngeal dysphagia patients on thickened fluids and determine factors affecting fluid intake. Dehydration was determined through food and fluid intake records taken by nurses, care aides, and volunteers. The authors did not specify how they confirmed that participants had dysphagia. Based on the results, the numbers of those with concurrent dysphagia and dysphagia can be ascertained.

Overall results

Demographic information regarding the participants of the 14 studies selected for qualitative synthesis and data pooling is shown in Tables 4 (heterogeneous samples) and 5 (restricted samples). Notably, three studies described malnutrition and dysphagia in participants who might not be considered elderly (20, 22, 33). There were also two studies that included participants who did not reside in LTC facilities (24, 26). Sample sizes ranged from 27 (26) to 136,794 (17).

The definitions and measures used to establish malnutrition differed greatly across studies. Of the 14 studies included in the qualitative synthesis and data pooling, five used BMI to determine nutritional status (14, 16, 17, 24, 26). However, each used a different BMI value as a cutoff to define nutritional concern (18.5, 20, 22, 23 and 24 kg/m^2). The remaining 9 studies used quite different methods of nutritional evaluation: weight loss over a specified period of
time (20, 22); common laboratory, serum and urinary tests as indices of hydration (32); vitamin (28), amino acid (31), and lymphocyte (30) levels; the standardized Mini Nutritional Assessment (18); and analysis of food and fluid intake records (33).

The definition and measures of dysphagia were also inconsistent across the studies included. Seven studies used tools to determine swallowing status: the FOSS, the Minimum Data Set (MDS), the Resident Assessment Instrument (RAI) and the Rehabilitation Institute of Chicago Clinical Evaluation of Dysphagia (16, 20, 26, 28, 30-32). However, each of these tools assesses dysphagia differently. The FOSS categorizes dysphagia according observed clinical signs, whereas the Rehabilitation Institute of Chicago Clinical Evaluation of Dysphagia calls for a more systematic evaluation. The RAI requires the healthcare professional to ask the resident about any difficulties swallowing, and includes an observation of the resident during meals, an interview with staff members across all shifts, a review of medical records, and an assessment of dental problems. The MDS asks one question that probes swallowing problems, namely, whether or not the person is on a texture modified diet. The remaining seven studies did not provide a definition for swallowing impairment, or any indication of how the determination of swallowing status was established (14, 17, 18, 22, 23, 33). Two of these seven studies stated that they provided participants with a questionnaire asking about swallowing (23, 24), however the details and psychometric properties of these questionnaires were not described.

At least some participants in every study reviewed were residents in long term care facilities or nursing homes. However, the level of institutional care, and consequently the comparability of resident characteristics across studies cannot be presumed. Terminology for different levels of care (e.g., LTC, assisted living, skilled nursing, complex continuing care) may be quite specific and may differ across regions and studies. Each of the 14 studies included in the qualitative synthesis and data pooling evaluated participants over the age of 65. All but five of the studies focused exclusively on those who were eating orally (17, 28, 30-32). The study by Flacker and colleagues (17) included 6.22% of participants (approximately 8,518 people) reported to use a feeding tube. Each of the studies by Leibovitz and colleagues (28, 30-32) included approximately half of their participants using some type of feeding tube. In these cases, it is unclear whether participants were receiving nutrition solely through the feeding tube, or if they were also taking some food and drink orally.
Table 4 displays frequency statistics for those who were found to have dysphagia and/or malnutrition across the studies with heterogeneous samples. The reported frequency of participants with dysphagia ranges from 7% (18) to 40% (23), while the percentage of those who were malnourished ranges from 12% (14) to 54% (17). Combining the total number of participants from studies with heterogeneous samples (274,017 participants), approximately 14% were found to have dysphagia, whereas approximately 33% were found to be malnourished. Only five of the eight studies with heterogeneous samples reported frequency data for the co-occurrence of malnutrition and dysphagia, which ranged from 3% (14) to 28% (23). Of the 136,005 participants in these five studies, 4% (or 4,727) residents were found to have both diagnoses concurrently. Table 5 provides frequency statistics for the co-occurrence of dysphagia and malnutrition in study samples recruited on the basis of either known dysphagia or known nutritional concerns. Given the nature of the restricted sample studies, pooled prevalence calculations were not performed, as the results would be skewed.
Table 4. Frequency data for dysphagia and malnutrition extracted from selected studies with heterogeneous samples

<table>
<thead>
<tr>
<th>First Author</th>
<th>Year</th>
<th>Title</th>
<th>Sample Size</th>
<th>Age of subjects</th>
<th>All subjects living in LTC?</th>
<th># of subjects with dysphagia</th>
<th># of subjects who were malnourished</th>
<th># of subjects with dysphagia + who were malnourished</th>
</tr>
</thead>
<tbody>
<tr>
<td>Challa</td>
<td>2007</td>
<td>Association of resident, facility, and geographic characteristics with chronic undernutrition in a nationally represented sample of older residents in U.S. nursing homes</td>
<td>128,514</td>
<td>60+</td>
<td>✓</td>
<td>23,633 (18%)</td>
<td>15,563 (12%)</td>
<td>3189 (3%)</td>
</tr>
<tr>
<td>Flacker</td>
<td>1998</td>
<td>A practical approach to identifying mortality-related factors in established long-term care residents</td>
<td>780</td>
<td>88.3±6.4</td>
<td>✓</td>
<td>67 (9%)</td>
<td>95 (12%)</td>
<td>unavailable</td>
</tr>
<tr>
<td>Flacker</td>
<td>2003</td>
<td>Mortality-related factors for 1-year survival in nursing home residents</td>
<td>136,794</td>
<td>65+</td>
<td>✓</td>
<td>12,821 (9%)</td>
<td>74,338 (54%)</td>
<td>unavailable</td>
</tr>
<tr>
<td>Jürschik</td>
<td>2010</td>
<td>High rates of malnutrition in older adults receiving different levels of health care in Lleida, Catalonia: an assessment of contributory factors</td>
<td>398</td>
<td>65+</td>
<td>✓</td>
<td>27 (7%)</td>
<td>127 (32%)</td>
<td>26 (7%)</td>
</tr>
<tr>
<td>Kumlien</td>
<td>2002</td>
<td>Stroke patients in nursing homes: eating, feeding, nutrition and related care</td>
<td>40</td>
<td>55-92</td>
<td>✓</td>
<td>9 (23%)</td>
<td>5 (13%)</td>
<td>unavailable</td>
</tr>
<tr>
<td>Morley</td>
<td>1994</td>
<td>Causes of weight loss in a community nursing home</td>
<td>156</td>
<td>51-105</td>
<td>✓</td>
<td>2 (7%)</td>
<td>30 (19%)</td>
<td>2 (7%)</td>
</tr>
<tr>
<td>Suominen</td>
<td>2005</td>
<td>Malnutrition and associated factors among the aged residents in all nursing homes in Helsinki</td>
<td>2114</td>
<td>mean = 82</td>
<td>✓</td>
<td>852 (40%)</td>
<td>613 (29%)</td>
<td>586 (28%)</td>
</tr>
<tr>
<td>Tannen</td>
<td>2012</td>
<td>Care problems and nursing interventions related to oral intake in German Nursing homes and hospitals: a descriptive multicentre study</td>
<td>5221</td>
<td>84.9±9.8</td>
<td>some</td>
<td>1368 (26%)</td>
<td>872 (17%)</td>
<td>924 (18%)</td>
</tr>
</tbody>
</table>
Table 5. Frequency data for dysphagia and malnutrition extracted from selected studies with restricted samples.

<table>
<thead>
<tr>
<th>First Author</th>
<th>Year</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Germain</td>
<td>2006</td>
<td>A novel dysphagia diet improves the nutrient intake of institutionalized elders</td>
</tr>
<tr>
<td>Leibovitz</td>
<td>2002</td>
<td>Homocysteine blood level in long-term care residents with oropharyngeal dysphagia: comparison of hand-oral and tube-ental-fed patients</td>
</tr>
<tr>
<td>Leibovitz</td>
<td>2004</td>
<td>CD4 lymphocyte count and CD4/CD8 ratio in elderly long-term care patients with oropharyngeal dysphagia: comparison between oral and tube feeding enteral feeding</td>
</tr>
<tr>
<td>Leibovitz</td>
<td>2005</td>
<td>Plasma levels of amino acids in elderly long term care residents with oropharyngeal dysphagia: comparison of hand-oral with tube-ental-fed patients</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sample Size</th>
<th>Age of subjects</th>
<th>All subjects living in LTC</th>
<th># of subjects with dysphagia</th>
<th># of subjects who were malnourished</th>
<th># of subjects with dysphagia + who were malnourished</th>
</tr>
</thead>
<tbody>
<tr>
<td>27</td>
<td>65+</td>
<td>some</td>
<td>17 (63%)</td>
<td>27 (100%)</td>
<td>17 (63%)</td>
</tr>
<tr>
<td>51</td>
<td>79.8±10.8</td>
<td>✓</td>
<td>51 (100%)</td>
<td>unavailable</td>
<td>unavailable</td>
</tr>
<tr>
<td>45</td>
<td>81.5±6.9</td>
<td>✓</td>
<td>45 (100%)</td>
<td>6 (21%)</td>
<td>6 (21%)</td>
</tr>
<tr>
<td>30</td>
<td>78.8±10.2</td>
<td>✓</td>
<td>30 (100%)</td>
<td>unavailable</td>
<td>unavailable</td>
</tr>
<tr>
<td>Author</td>
<td>Year</td>
<td>Study Description</td>
<td>Participants</td>
<td>Dehydration Rate</td>
<td>Oral Fluid Intake</td>
</tr>
<tr>
<td>------------</td>
<td>------</td>
<td>------------------------------------------------------------------------------------</td>
<td>--------------</td>
<td>-----------------</td>
<td>------------------</td>
</tr>
<tr>
<td>Leibovitz</td>
<td>2007</td>
<td>Dehydration among long-term care elderly patients with oropharyngeal dysphagia</td>
<td>95</td>
<td>80.0±7.8</td>
<td>✔</td>
</tr>
<tr>
<td>Ramage</td>
<td>1998</td>
<td>Determine the oral fluid intake of oropharyngeal dysphagia patients on thickened fluids and determine factors affecting fluid intake</td>
<td>29</td>
<td>18-95</td>
<td>✔</td>
</tr>
</tbody>
</table>
Discussion
After a thorough search of the literature and the application of a strict set of inclusion criteria, 14 studies detailing malnutrition and dysphagia in long term care were analyzed and synthesized. While it is obvious that both malnutrition and dysphagia exist amongst residents in LTC settings, the exact prevalence of these conditions individually, or their co-occurrence is currently unknown and cannot be clearly determined from the articles reviewed. Reasons for the differing impressions regarding co-occurrence of dysphagia and malnutrition in LTC are discussed below.

Definitions
The varying definitions used to classify malnutrition and dysphagia are a clear reason for differing rates of occurrence of these conditions to be reported across the studies reviewed. For example, as previously mentioned, among the five studies using BMI measures to classify nutritional status, five different BMI cutoff values were used as thresholds differentiating malnutrition from acceptable nutrition. Based on the information provided, it is not possible to determine what impact a common BMI cutoff value might have had on the rates of malnutrition prevalence across these studies, nor how the additional use of a BMI cutoff might have impacted the understanding of malnutrition prevalence in the remaining nine studies using different methods to measure nutritional status. Challa and colleagues (14) were the only authors to use the WHO definition of malnutrition. Furthermore, it is not clear whether dehydration was considered to be a form of malnutrition in all studies, and common measures of hydration status (such as blood and urine samples) were not applied uniformly across the studies reviewed.

The definition of dysphagia also varied across the studies included for qualitative synthesis and data pooling. Seven of the 14 studies provided a very vague definition, without detailing how swallowing status was determined. The other seven studies used measures that differ in their methods of evaluation. If a single, standardized measure of swallowing status had been applied across all studies analyzed, the results might have been very different. It is evident that in order to synthesize information effectively, standard definitions of both nutritional and swallowing status need to be established.
Sample Size

There was no apparent pattern between sample size and the frequency of those identified to have either malnutrition and/or dysphagia. One might assume that larger samples, such as those seen in the studies by Challa and colleagues (14) and Flacker and colleagues (17), might be more representative of LTC population in general, although they both draw on the relatively indirect data found in MDS records. However, even these two studies reported prevalence statistics that differed greatly. Challa (14) reported that 18% of participants in their sample presented with dysphagia and 12% of participants were malnourished, whereas Flacker (17) reported that 9% of participants presented with dysphagia and 54% of participants were malnourished. These differences in the apparent frequencies of dysphagia and malnutrition may be attributable to varying definitions, as mentioned previously.

Three of the studies reviewed included participants under the age of 65, extending as young as 18. However, it is difficult to determine whether and how age may have skewed the results based on the pooled groupwise reporting of the data. Similarly, results from the five studies including participants who were being tube-fed may also be skewed. There were also two studies (24, 26), including some participants who were reported to reside outside LTC facilities, but providing insufficient detail to enable the reader to isolate these non-residents from the LTC resident portion of the sample. This too could have skewed the data, resulting in an inability to generalize the results to the LTC population at large.

The studies with restricted samples (26, 28, 30-33) have sample sizes that are less varied, ranging from n = 27 to n = 95. Nevertheless, there is still little consistency between the reported frequencies of the co-occurrence of dysphagia and malnutrition. The different sampling strategies used to recruit participants in these studies likely play a role in the variation seen within results. For example, Germain and colleagues (26) included participants in whom malnutrition was already established. Similarly, Leibovitz and colleagues (32) included only participants who had already been diagnosed with oropharyngeal dysphagia. The study by Kumlien et al. (20) further restricted their study to individuals with a history of stroke, although the type and location of stroke, which can impact the likelihood of dysphagia (34), was not specified. Due to these differences in inclusion criteria, these restricted samples cannot be considered representative of the population of adults living in LTC in general.
Conclusion
Based on a careful review of the literature and compilation of frequency data regarding the prevalence of malnutrition and dysphagia in LTC across several studies, evidence of the co-occurrence of malnutrition and dysphagia emerges. Due to discrepancies in the methods used to describe and measure both malnutrition and dysphagia across studies, it is difficult to determine the prevalence of either condition separately, or together. For researchers and clinicians alike, the impact of dysphagia on malnutrition must be seriously considered. Future research should focus on standardization of terminology and measurement instruments in order to help elucidate the current problem. If the relationship between dysphagia and malnutrition can be described in more detail, clinicians and researchers can understand the extent to which dysphagia contributes to malnutrition and begin to develop evidence-based practices to aid in ameliorating this cause of malnutrition in LTC settings. Successful intervention to limit dysphagia as a cause of malnutrition has the potential to improve the quality of life for residents, and possibly reduce hospital admissions and associated healthcare costs.
References


Chapter 3
The Effect of Tongue Strength on Meal Consumption in Long Term Care

Post-hoc analyses of effect size using Cohen’s $d$ can be found in Appendix B.

Abstract

**Purpose:** As many as 74% of residents in long-term care (LTC) are anticipated to have swallowing difficulties (dysphagia). Low food intake is commonly reported in persons with swallowing problems, but food intake may also be affected by fatigue in the swallowing muscles. As fatigue sets in during mealtimes, the strength of the tongue may decline. Tongue strength is also known to decline with age but it is unclear how this functional change may influence food intake. In this pilot study, we explored the relationship between tongue strength and meal consumption in persons not previously diagnosed with dysphagia.

**Methods:** The Iowa Oral Performance Instrument was used to collect maximum anterior isometric tongue-palate pressures from 12 LTC residents (5 male; mean age: 85, range 65-99). Residents were also screened for dysphagia with applesauce and a water swallow test. Each resident was observed at three different meals to record the length of time taken to eat the meal, amount of food consumed, and any indication of overt signs of swallowing difficulty (e.g. coughing).

**Results:** Residents who displayed observable swallowing difficulties at mealtimes had significantly lower tongue strength than those without swallowing difficulties ($p < 0.01$). Those with lower tongue strength took significantly longer to complete meals ($p<0.05$) and consumed less food. Tongue strength was not predictive of performance on the water screen and the water swallow test was not a good predictor of which participants were observed to display mealtime difficulties.
Conclusion: Among seniors in long term care, reduced tongue strength is associated with longer meal times, reduced food consumption, and the presence of observable signs of swallowing difficulty. Further exploration of these relationships is warranted.

Introduction
Elderly adults living in long term care (LTC) facilities (including nursing homes and assisted living), are nutritionally vulnerable. Inadequate food and fluid intake leads to malnutrition. Malnutrition is estimated to be present in 30-60% of those living in LTC, with negative consequences for health, well-being, quality of life (QOL) and health care costs [1]. Malnutrition can also lead to serious illnesses, which may call for hospitalization. In Canada, admissions from LTC account for approximately 10% of all acute care hospital visits [2]. As the baby-boomers age, an increased demand for LTC beds is anticipated [3]. In the European Union (EU), elderly people currently account for approximately 18% of the population [4] and the old-age dependency ratio (i.e., the number of people over 65 divided by the number of people aged 15-64) is expected to reach 53% by 2050 (up from 25% in 2007) [5]. These demographic changes will place serious pressures on the healthcare system, which will be exacerbated by malnutrition unless effective solutions for poor food intake in LTC are found. In order to limit and mitigate the costs associated with malnutrition, it is critical that we determine the factors associated with and contributing to poor food intake and malnutrition among those residing in LTC.

Poor food and fluid intake is the primary cause for LTC malnutrition; average consumption has been estimated at 50% of food offered [6]. Dysphagia (swallowing difficulty) is also a known comorbidity for those in LTC, and estimated to be present in as many as 74% of residents [7, 8]. There is an even higher prevalence of dysphagia in those with dementia [9], who comprise a large proportion of LTC residents. Residents with dysphagia are at increased risk for inadequate food intake, leading to malnutrition [10]. Food intake may also be affected by eating-related fatigue [11] and this may be of particular concern in seniors with dysphagia, who are reported to take longer to eat [12].

The tongue is a critical organ in swallowing, providing the driving forces that transport food and liquid through the mouth and pharynx. Fatigue in the tongue muscles may contribute to incomplete food clearance (residue), prolonged time to complete a meal and reduced intake. In a
study by Kays and colleagues [13] the tongue strength of older, healthy adults (aged 65-82) was measured twice at baseline and once following consumption of a meal. The results showed that the activity of eating a meal can be tiring enough to cause a reduction in post-meal measures of tongue strength compared to pre-meal measures. Previous studies have also shown that tongue pressures are generally lower in healthy older adults when compared to healthy younger adults [14-18], and reduced tongue strength is associated with aspiration (i.e., entry of material into the airway, contributing to the risk of respiratory consequences) [19]. However, we do not know the extent to which tongue strength impacts food intake in elderly individuals living in LTC. If an age-related reduction in tongue strength increases the demands of dining for those in LTC, we may see longer mealtimes, leading to reduced intake and contributing to malnutrition risk.

The goal of the current pilot study was to explore tongue strength in elderly residents in a LTC facility and to measure its association with: (a) signs of swallowing impairment based on a dysphagia screening tool; (b) length of time to eat a meal; (c) signs of swallowing impairment observed during meals; and (d) amount of food consumed. The study was also conducted to establish feasibility of collecting these measures in a larger, future study. We hypothesized that those with reduced tongue strength would be more likely to demonstrate signs of swallowing impairment on the dysphagia screening tool, take longer to finish eating, show signs of swallowing impairment during meals, and eat less than residents with tongue strength within the reported norms.

Materials and Methods

Participants
A pilot sample of 20 elderly residents (8 male, 12 female; mean age: 85, range 65-99) was recruited from a LTC facility in Waterloo, Canada as part of a larger project exploring predictors of malnutrition. Informed written consent was obtained directly from LTC residents who had the capacity to consent as identified by unit staff. For residents who did not have the capacity to provide informed consent, unit managers or designates approached substitute decision makers using a standard script for permission to provide their contact information to the researchers. In the cases where a substitute decision maker provided consent for participation, assent to participate in the study was evaluated by the willingness of residents to cooperate with data collection procedures. The inclusion and exclusion criteria for participants
can be found in Table 1.

Table 1. Inclusion and exclusion criteria for larger pilot study exploring predictors of malnutrition

<table>
<thead>
<tr>
<th>Inclusion</th>
<th>Exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>• 65 + years of age</td>
<td>• Medically unstable</td>
</tr>
<tr>
<td>• Required at least two hours per day of nursing care due to dependence</td>
<td>• Required tube-feeding</td>
</tr>
<tr>
<td>in activities of daily living</td>
<td></td>
</tr>
<tr>
<td>• Had resided in the home for at least two months</td>
<td>• Not eating because they were receiving palliative care</td>
</tr>
<tr>
<td>• Functional communication in English</td>
<td>• Had advanced directives excluding them from research</td>
</tr>
<tr>
<td>• Either they or their substitute-decision maker could provide consent</td>
<td></td>
</tr>
<tr>
<td>to participate.</td>
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</table>

A subset of these 20 pilot participants was recruited to perform the swallowing screening and tongue strength measures. In total, twelve elderly adults (5 male, 7 female; mean age: 85, range 65-99) made up this smaller group of residents. The inclusion criteria for this subset can be found in Table 2.

Table 2. Inclusion and exclusion criteria for participants in swallow screening experiment

<table>
<thead>
<tr>
<th>Inclusion</th>
<th>Exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Had a diet prescription that permitted them to drink thin liquids at</td>
<td>• Dysphagia diet (i.e. prescribed to drink thickened liquids during meals)</td>
</tr>
<tr>
<td>mealtimes</td>
<td>• Unable to follow commands</td>
</tr>
<tr>
<td>• Alert and responsive</td>
<td></td>
</tr>
<tr>
<td>• Able to sit upright</td>
<td></td>
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<tr>
<td>• Able to follow simple, one-step directions</td>
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</table>

Swallowing screening and tongue strength
Each participant in the study was screened for dysphagia by a licensed speech-language pathologist (SLP) using a modified version of the Screening Tool for Acute Neurological Dysphagia (STAND) [20]. This tool evaluates a participant’s risk of dysphagia using pureed fruit (Mott’s® Fruitsations Unsweetened Applesauce) and water (Nestle® Pure Life Bottled Water). The modifications adopted for the purposes of this pilot study were as follows:
1) Each participant was asked to repeat the initial task of swallowing a teaspoon of puree (applesauce) three times to ensure representative sampling of swallowing behavior. The puree task was discontinued if any difficulties were noted.

2) Two saliva swallows were elicited after completion of the puree trials, regardless of the number of puree trials completed. Thicker consistencies are known to cause increased residue [21]; therefore, these saliva swallows were included for the purpose of clearing any residue prior to the water swallow portion of the test.

3) A single 3-ounce water swallow trial was performed, requiring residents to drink water from a cup. The additional straw-drinking 3-ounce water swallow trial specified in the original STAND protocol was omitted.

4) Oxygen saturation levels were not monitored, and tearing in the eyes was not used as a sign of swallowing difficulty since these signs have not been found to be valid indications of swallowing impairment in the broader swallowing literature [22, 23].

5) Lastly, the observation of more than two swallows per bolus was added as a sign of swallowing difficulty [24].

Measures of tongue strength were taken by the SLP using the Iowa Oral Performance Instrument (IOPI). The IOPI is a handheld manometry system that consists of a 2.7 ml air-filled bulb that is squeezed between the tongue and the hard palate (see Figures 1 and 2). Pressures are displayed on the device LCD screen, in kilopascals. The bulb is attached to the IOPI machine with a small, clear connector tube, which also prevents the bulb from being swallowed accidentally. A clean, individually wrapped, single-use tongue pressure bulb was used for each participant, and disposed of immediately after use. In consultation with the manufacturer, we have developed a Microsoft Excel software program to register a digital pressure waveform from the analog signal generated by the IOPI at 250 Hz. This enables us to provide a biofeedback screen view of the tongue pressure measurement to the participant during data collection and to extract detailed measures of tongue pressure amplitude and timing from the recorded waveform (Figure 3). Both maximum anterior isometric tongue strength pressures (squeezing the bulb between the front of the tongue and the hard palate as hard as possible) and saliva swallow pressures (keeping the bulb at the front of the tongue while swallowing saliva) were collected three times from each participant. Each participant was allowed to practice two times before any data were collected. Tongue pressure tasks were cued with a 10 second rest
between each task repetition; total time to complete these tasks was three to five minutes.

Swallowing screening and tongue pressure tasks were completed in a single session for all residents. Measures were taken between meals and typically in the morning when residents were most alert. The unit kitchen served as the most accessible place to complete all of the tasks. Any participants who were unwilling or unable to follow the instructions to perform the tasks were excluded.

Figure 1. The Iowa Oral Performance Instrument (IOPI), a hand-held device to measure tongue pressures.

Figure 2. Sample of a waveform from maximum anterior isometric tongue pressures.
Meal observations

Three separate meals were observed on the same day for the purposes of determining food intake for each participant. Two trained research assistants (RA) worked in tandem to collect meal observations from five residents per meal. Observations included:

- weighing all items individually on the main plate, before and after the resident was finished and estimating intake of other meal components based on the standard portions provided (e.g. beverages, side dishes);
- documenting mealtime processes (e.g. length of time to eat the meal, number of assistants helping the resident, etc.);
- documenting any eating assistance provided; and
- completing a checklist of mealtime behaviours of the resident and staff who interacted with the resident.

Food weighing was completed by one research assistant, who was located next to the servery, with measures recorded in grams using a calibrated digital balance (Ohaus V22PWE3T, ITIN Scale Company, Brooklyn, NY). The second research assistant monitored other mealtime data collection while main dishes were being plated. When a resident finished their main plate, it was retrieved by the assistants and put aside for weighing of waste after the meal service was complete. The difference between plated and leftover food, was captured as the amount ‘consumed’ and the total weight of the main plate items only were used in this analysis. Length of time at the meal was determined by identifying the difference between “start time” (defined as the latest of: a) the time when the resident arrived; or b) when food/beverages were made available for consumption at the table) and “end time” (defined as the earliest of: c) the time when the resident left the meal and did not return; or d) when all food provided to the patient had been consumed. The Edinburgh Feeding Evaluation in Dementia (EdFED) scale was used to document mealtime eating skills and difficulties [25]. This validated instrument consists of ten questions which are scored as occurring 1(never), 2 (sometimes) or 3 (often). An overall score of greater than 10 is considered indicative of mealtime difficulties. As this tool does not directly assess all mealtime challenges, including signs of swallowing difficulties, an additional nine questions were created (e.g. does the resident receive verbal prompting to eat). Two questions are focused on swallowing signs (Does the resident cough during the meal? Does the resident choke during the meal?). These additional items were scored to be consistent with the EdFED.
A list of the questions can be found in Table 3.

**Table 3. EdFED and additional questions to evaluate mealtime difficulties**

<table>
<thead>
<tr>
<th>EdFed Questions</th>
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<tbody>
<tr>
<td>1. Does the resident require close supervision while feeding/eating?</td>
</tr>
<tr>
<td>2. Does the resident require physical help while feeding/eating?</td>
</tr>
<tr>
<td>3. Is there spillage while feeding/eating?</td>
</tr>
<tr>
<td>4. Does the resident tend to leave food on the plate at the end of the meal?</td>
</tr>
<tr>
<td>5. Does the resident ever refuse to eat?</td>
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<tr>
<td>6. Does the resident ever spit out his food?</td>
</tr>
<tr>
<td>7. Is there spillage of food out of the mouth?</td>
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<tr>
<td>8. Does the resident ever turn his head away while being fed?</td>
</tr>
<tr>
<td>9. Does the resident refuse to open his mouth?</td>
</tr>
<tr>
<td>10. Does the resident refuse to swallow?</td>
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</table>

**Additional questions regarding eating behaviours**

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<table>
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<tbody>
<tr>
<td>1. Does the resident receive close supervision while feeding/eating?</td>
</tr>
<tr>
<td>2. Does the resident receive verbal prompting to eat?</td>
</tr>
<tr>
<td>3. Does the resident use adaptive utensils to eat?</td>
</tr>
<tr>
<td>4. Does the resident appear distracted e.g. watching TV, or people, repetitive behaviours thereby seeming to forget the food in front of them?</td>
</tr>
<tr>
<td>5. Does the resident treat the food in an unusual way e.g. repetitive behaviours of manipulating food without eating, doing strange things with food such a pouring liquid onto plate, etc.?</td>
</tr>
<tr>
<td>6. Does the resident lack energy to eat?</td>
</tr>
<tr>
<td>7. Does the resident appear to have chewing problems?</td>
</tr>
<tr>
<td>8. Does the resident cough during the meal?</td>
</tr>
<tr>
<td>9. Does the resident choke during the meal?</td>
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**Analysis**

Descriptive statistics (means and 95% confidence intervals) were obtained for the tongue strength and saliva swallow pressure measures as well as for mealtime, and daily consumed food weight. Frequency statistics were calculated for the categorical variables of presence/absence of signs of swallowing impairment on the STAND dysphagia screening tool and the swallowing signs observed at meals. Any single observation of swallowing difficulty across any of the three meals was sufficient to result in a code of swallowing signs being ‘present’. Differences in tongue strength were explored between participants with and without signs of swallowing impairment using one-way analyses of variance (ANOVA) with repeated measures. Participants were then stratified into two groups according to whether their maximum tongue strength measures fell above or below the lower 95% confidence interval boundary.
(normal; reduced tongue strength). Differences between the two tongue strength groups were explored using univariate ANOVAs for the mealtime measures of: a) time required to complete a meal (averaged across the 3 meals); and b) daily amount of food consumed across the 3 meals. The relationship between meal duration and amount of food consumed was explored using scatter plots and linear regression. Significant effects were further explored with post hoc analyses of effect size using Cohen’s $d$ (see Appendix B).

**Results**

Table 3 summarizes the means and 95% confidence intervals for the tongue-pressure parameters of interest, calculated based on three repetitions of each task obtained from each participant.

<table>
<thead>
<tr>
<th>Table 3. Maximum tongue pressure measures.</th>
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<tbody>
<tr>
<td>Mean</td>
</tr>
<tr>
<td>------</td>
</tr>
<tr>
<td><strong>Maximum Tongue Strength (kPa)</strong></td>
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<tr>
<td><strong>Maximum Saliva Swallow Pressure (kPa)</strong></td>
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</tbody>
</table>

None of the participants showed difficulties on the puree (applesauce) or the saliva swallow components of the modified STAND. Two of the 12 participants failed the swallow screen based on the fact that they displayed difficulties on the 3-ounce water swallowing challenge. Maximum isometric tongue strength was notably lower in one of these two participants (13 kPa vs. overall mean of 35 kPa), however as a pair, these two participants did not display significantly lower tongue strength measures than those seen in participants who passed the water swallowing challenge: $F(1, 10) = 0.442, p = 0.52$.

Four participants displayed signs of swallowing impairment at mealtimes. As a group, these residents had reduced maximum isometric tongue strength (mean: 17 kPa, 95% confidence interval: 7-27) compared to those without swallowing difficulties (mean: 37 kPa, 95% CI: 29-
44) (Figure 4). This difference was statistically significant: F(1, 10) = 12.97, p < 0.005.

Figure 3. Graph showing that those with mealtime evidence of swallowing problems had significantly lower tongue strength than those who displayed no evidence of mealtime difficulties.

Those with lower tongue strength also took an average of 20 minutes longer than participants with normal tongue strength to complete meals: (82 minutes vs. 62 minutes; F(1, 9) = 5.81, p = 0.04. The estimated amount of food consumed, in grams, did not differ between individuals with reduced versus normal tongue strength (p = 0.1). However, meal duration showed a significant negative correlation with food consumption; reduced daily food intake of the main plate items was associated with significantly longer mealtimes, as illustrated in Figure 5 (r = -0.63, p = 0.04; r²=0.39).
Figure 4. Scatterplot displaying the relationship between time to eat a meal, daily amount of food consumed and tongue strength. Those with lower tongue strength tended to take longer to eat and ate less than those with higher tongue strength.

Discussion
These results illustrate that reduced anterior maximum isometric tongue pressures may be a good predictor of dysphagia and mealtime difficulty for residents living in LTC. Based on the current study, there is a clear disparity in tongue strength between those who displayed observable swallowing difficulties at mealtimes and those who did not. The participants formed two discrete groups: one with anterior MIPs below 28 kPa and another group with anterior MIPs above 28 kPa. The group with lower tongue strength displayed difficulties at the meal, whereas the group with relatively higher tongue strength displayed no mealtime difficulties. The tongue plays a critical role in bolus transport from the oral cavity to the pharynx. Appropriate tongue strength is crucial to help avoid problems like residue and aspiration (entry of material into the airway). Given the tongue’s significant contributions to swallowing, it is logical that reduced tongue strength might be predictive of mealtime difficulties.

The literature suggests that healthy elderly adults should have anterior maximum isometric pressures (MIPs) of at least 40kPa [14, 15, 26, 27], and saliva swallow pressures
between 20 and 30 kPa. The average anterior MIPs of the elderly residents in this study fell slightly below normative values, but the saliva swallow pressures for this group tended to fall within the normative range [15]. This is consistent with previous literature that has reported a decrease in tongue pressure MIPs in elderly individuals [15, 17, 26-28]. These age-related decreases in tongue pressure may be indicative of sarcopenia of the tongue. Sarcopenia generally results from a decrease in the size and number of muscle fibers and an increase in noncontractile tissue, which could result in a less mobile tongue [27].

Anterior tongue strength also proved to be predictive of length of time to eat a meal and the daily amount of food consumed. Although seemingly logical, those who had lower tongue strength generally took longer to eat a meal and ate less than those with higher tongue strength. Food intake might also be affected by fatigue, as this is a commonly reported condition of older adults [11, 13, 29]. A major complaint of many seniors with dysphagia is that it takes them a longer time to eat than others, possibly due to fatigue; one result of this is limited food intake [12]. Considering that the muscles of the tongue are active participants in the swallowing process, it would be expected that as muscle fatigue sets in, the strength of these muscles will decline and eating may become a more arduous task. This could also lead to reduced ingestion, contributing to malnutrition over time. Previous research has shown that the activity of eating a meal can be tiring enough to cause a reduction in post-meal measures of tongue strength in healthy elderly individuals [13]. Therefore, if tongue strength is already low for LTC residents at baseline, then it is possible that tongue strength will decline further during mealtimes and directly impact the length of time to eat a meal and the amount of food consumed.

It is interesting to note that none of the residents in this pilot study had difficulty with the puree or saliva swallow components of the modified STAND dysphagia screening tool. Those that failed showed difficulties on the water swallow component of the test only, and only one of these two people showed any overt difficulties at meals. Furthermore, three persons with observable choking or coughing during meals were not identified by this screening task. Moreover, those with low tongue strength did not necessarily fail the water swallow screen. Although widely used, the water swallow screen does not appear to be helpful in predicting those with functional swallowing difficulties in a LTC setting. The 3-ounce water swallow test is typically used to determine if thin liquids and all other food consistencies can be taken safely (i.e., without aspiration), and is reported to have high sensitivity (100%) and low specificity.
In those with dementia [29], who make up approximately 70% of the LTC population [7]. Despite the small sample size in the current study, this same test was not found to be a good predictor of the more direct observation of mealtime difficulties. The study by Suiter & Leder [29] that reported high sensitivity and low specificity of the water test evaluated difficulties under strict testing conditions, after using a fiberoptic endoscopic evaluation of swallowing (FEES) to predetermine swallowing status. The testing environment and the presence of a scope through a naris and down the oropharynx may have skewed the results of their study. Further, the validity of Suiter and Leder’s water test findings was potentially criterion biased by the fact that the FEES exam had already been completed and the results were known to the examiners.

**Limitations**

There are some limitations to note for the current study. The first, is that this was a pilot study including a very small sample of the LTC population; results might vary with a larger sample size. Moreover, the LTC residence from which the pilot participants were recruited may not be representative of all LTC homes. The current study did not make comparisons based on cognitive impairment or oral health status, however all participants had sufficient cognitive function to follow study instructions. Medications were also not considered in this study, and these may have affected appetite, lethargy at meals and time for meal consumption. Meal duration measures did not subtract bathroom breaks or prolonged periods of time when the resident might not have been eating. This may have inflated the length of the mealtimes measured. The amount of food consumed and used in this analysis was simply the weight of the main plate that was eaten; it does not provide a complete picture of all of the foods and fluids provided at the meal. It would be interesting to further explore the types of food consumed in entirety (e.g. meat, pudding) as it can be hypothesized that foods that are more challenging to might contribute to greater fatigue and longer mealtimes.

**Conclusions**

In conclusion, in this pilot study, tongue pressure measurement has been shown to hold promise as an indicator of poor meal consumption for elderly residents in long term care. There was a clear difference in tongue strength between LTC residents who showed signs of swallowing difficulty at mealtimes and those who did not. Reduced tongue strength was also associated with
longer meal times, reduced food intake and the presence of observable choking and coughing at the meal. Although widely used, the 3-ounce water swallow test does not appear to identify those who show these clinical signs of swallowing difficulties. Further exploration of these relationships and the potential to improve food intake using tongue strength training is warranted.
References


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Chapter 4
The Relationships Between Malnutrition, Dysphagia, Tongue Strength and Mealtime Outcomes in Long Term Care

Introduction
The fastest growing segment of the population in Canada is the elderly (Statistics Canada, 2012), and they have the highest rate of illnesses, disability, and admission to hospital. Malnutrition plays both a contributing and complicating role in these conditions, but this is often under-recognized by healthcare professionals (Dudek, 2000; Reuben, Effros, Hirsch, Zhu, & Greendale, 1999 Zhu, & Greendale, 1999; Thomas, Ashmen, Morley, & Evans, 2000). Nutrition-related factors such as weight loss, undereating, obesity, diabetes and sarcopenia can precipitate admission to long term care homes (LTC) (Bourdel-Marchasson, Helmer, Fagot-Campagna, Dehail, & Joseph, 2007; Bourdel-Marchasson et al., 2004; Zizza et al., 2003). The estimated prevalence of malnutrition in LTC homes ranges from 12% to 54% (Namasivayam & Steele, 2015). The broad range of this estimate may be attributed to the paucity of high-quality literature and lack of standard definitions (Namasivayam & Steele, 2015), as well as the wide variety of LTC homes (e.g. public versus private, rural versus urban, cultural versus multicultural, etc.). Several resident-level risk factors for malnutrition in LTC have been cited, including social isolation, depression, dementia, poor dentition, multiple medications and dysphagia (swallowing impairment) (Chapman, 2006), however, how each of these factors contributes to malnutrition is not well understood.

Dysphagia is another concern for seniors living in LTC, independent of malnutrition, as it is a known comorbidity of dementia (Logemann, 2003) and a large majority of LTC residents are affected by dementia with varying degrees of severity. Dysphagia has been reported to hinder medical recovery in the elderly, leading to longer hospitalizations and an increased need for LTC (Odderson, Keaton, & McKenna, 1995). A common sequela of dysphagia, aspiration pneumonia, is also associated with a significant risk of morbidity and mortality (Shariatzadeh, Huang, & Marrie, 2006). When present, dysphagia is commonly assumed to contribute to malnutrition risk, but there is little direct evidence of this relationship in the literature regarding LTC. A recent systematic review on malnutrition and dysphagia in LTC found some evidence of co-occurrence, with estimated prevalence ranging from 3% to 28%. However, a lack of
standard definitions and measures for both malnutrition and dysphagia limited the ability to
draw objective conclusions (Namasivayam & Steele, 2015). If we can establish the extent and
nature of the relationship between dysphagia and malnutrition in LTC, this will determine
whether screening for both conditions should be recommended and whether assessment for one
condition should be recommended as a rule in individuals recognized to have the other
condition. It is also possible that interventions to treat or prevent dysphagia may have secondary
benefits of helping to prevent malnutrition, or vice versa.

The tongue plays a primary role in swallowing, contributing to the formation, placement,
and manipulation of the bolus within the oral cavity, and generating the forces that propel a
bolus into and through the pharynx (Youmans & Stierwalt, 2006). Several studies suggest that
tongue strength declines with age (Crow & Ship, 1996; Fei et al., 2013; Youmans, Youmans, &
Stierwalt, 2009), and in adults with dysphagia (Konaka et al., 2010; Lazarus et al., 2000; Steele
et al., 2013; Yeates, Molfenter, & Steele, 2008; Yoshida et al., 2006). Associations have been
made between tongue weakness and aspiration (i.e. entry of food or drink into the airway during
swallowing) in healthy community dwelling seniors (Butler et al., 2011), and this same
relationship may exist for older adults living in LTC. In one preliminary study performed in
LTC, correlations were found between low tongue strength and several measures of mealtime
function, including longer mealtime durations, reduced food and drink intake, and increased
prevalence of mealtime difficulties (Namasivayam, Steele, & Keller, 2016). In another study,
tongue strength was shown to decline over the course of a meal in seniors (Kays, Hind,
Gangnon, & Robbins, 2010). Reduced tongue strength may, therefore, be a factor contributing
both to dysphagia and to malnutrition.

The purpose of the current study was to study the associations between: a) nutritional
status; b) mealtime measures of food intake; c) clinical signs suggesting the presence of
dysphagia; and d) reduced tongue strength in a large sample of older adults living in LTC. We
hypothesized that signs of dysphagia would be associated with malnutrition, and that reduced
tongue strength would be associated with signs of dysphagia. Based on a previous pilot study
(Namasivayam et al., 2016), we expected to find that tongue weakness would be associated with
longer mealtime durations and reduced food intake. Given the hypothesis that reduced tongue
strength would be associated with the presence of dysphagia, we expected that similar findings
for mealtime duration and food intake would be seen in individuals with suspected dysphagia.
Methods
This study was conducted as a part of a larger study known as M3: Making the Most of Mealtime. The larger M3 study was a cross-sectional, multi-site study involving data collection in four provinces across Canada: New Brunswick, Ontario, Manitoba and Alberta. Human subjects ethics clearance was obtained from the Research Ethics Boards of the Universities of Alberta, Manitoba, Moncton and Waterloo, as well as the University Health Network in Toronto. In some cases, approval was also required and received from review boards inside the individual LTC homes.

Participants
A total of 639 residents (199 male; mean age: 86.8±7.83, range: 62 – 107) were recruited from 32 LTC homes across Canada (8 homes per province). Within each province, LTC homes were purposively sampled to ensure a diverse and representative sample with respect to facility size (minimum of 50 residents), model of care, profit-status (for profit = 10, not for profit = 22), cultural factors, rural/urban region and other home-level determinants that might impact food intake (Strathmann et al., 2013). Within each LTC home we recruited residents from up to 3 randomly selected care units, with a care unit defined as a geographic area in a LTC home, having a consistent, assigned group of direct care providers and, typically, its own dining area. In each home, we ensured the inclusion of at least one dementia specific unit, if such a designation existed for the home. All residents within these units, regardless of cognitive ability, were eligible to participate if they: were over the age of 65 years; required at least 2 hours per day of nursing care; had resided in the home for at least 1 month; and, either they or their substitute decision maker provided consent to participate. Residents were excluded if they were currently medically unstable (i.e., within 1 month of acute care hospitalization); were on a short-term admission (e.g., respite care); required tube feeding; were not eating because they were at the end of life; or had advanced directives excluding them from research. Home staff identified those who met these criteria (Aghdassi et al., 2007). A random number table was used to determine the order in which eligible residents from each unit should be approached by home staff to inquire whether they were interested in hearing more about the study from research staff. For residents who were not considered competent their alternative decision maker was approached. Informed written consent was obtained directly from residents who were identified by unit staff as having the capacity to consent, or from substitute decision makers from those
considered to lack capacity. Continued assent to participate was confirmed throughout data collection, based on the willingness of residents to cooperate with data collection procedures (Slaughter, Cole, Jennings, & Reimer, 2007).

**Measures and Data Collection**
Data were collected between January and December 2015. The data collection team in each province included a coordinator (a registered dietitian or individual with dietetics training and applied nutrition research experience), and two post-graduate research associates (RAs) who were trained to collect food intake and meal observation data.

**Nutritional Status**
Data on age, gender, cognition, health, nutritional status and potential risk factors for poor food intake were collected at the resident-level. Nutritional status was assessed using a version of the Patient-Generated Subjective Global Assessment (PG-SGA) (Bauer, Capra, & Ferguson, 2002; Keith, 2008), tailored to the LTC environment, as described in the M3 protocol (Keller et al., under review). Residents were classified either as adequately nourished (diagnostic category A), moderately or suspected of being malnourished (diagnostic category B), or severely malnourished (diagnostic category C) (Detsky et al., 1987). The PG-SGA inquired about changes in weight, dietary intake, gastrointestinal symptoms, functional capacity, as well as a physical examination of subcutaneous fat, muscle wasting, edema and ascites. Diagnostic categories B and C were collapsed, so that those who were determined to be in one of these two categories were deemed to be malnourished and residents falling under category were deemed to have no nutritional concerns.

**Food Intake and Mealtime Measures**
Three nonconsecutive days of meal observation, including a weekend day, were used to measure the food intake of participants, with residents observed at 3 meals each day, for a total of 9 meal observations per resident. Estimates of caloric intake were based on nutrient analysis of the facility menu, using *The Food Processor Software* from ESHA Research (version 10.14.2). This process is further described in the M3 protocol (Keller et al., under review). Estimates of additional food and fluid intake at snack times and between meals were included, based on inquiries with the residents, family and/or staff. Site staff were asked to report before-breakfast food consumption and were trained to record evening snacks and beverage intake on food intake
assessment days. Other mealtime measures, such as mealtime duration (MTD) were recorded at each meal. In addition, a more elaborate mealtime observation was conducted for each resident at one meal per observation day (3 observations total). This detailed mealtime observation included the documentation of mealtime behaviours, such as coughing and choking.

**Dysphagia Status**

Dysphagia status was a composite variable, determined on the basis of three different input variables. First, individuals who were already receiving thickened liquids were considered to have possible dysphagia. Second, with the exception of residents already receiving thickened liquids, all other participants who were cognitively aware completed a swallow screen using the Screening Tool for Acute Neuro Dysphagia (STAND) (Shephard, 2007). Residents consumed three teaspoons of applesauce and drank 90 ml of water in a continuous fashion. If signs of dysphagia (i.e., coughing, wet voice quality, throat clearing) were noted at any point during the test, the test was stopped and it was noted that the resident required a more comprehensive dysphagia evaluation. Third, any single observation of coughing or choking across any of the three meals where mealtime behaviours were observed for any resident was sufficient to result in a code of swallowing signs being ‘present’. Documentation of a swallowing concern through any one of these three mechanisms resulted in a resident being classified as having suspected dysphagia.

**Tongue-Strength**

The investigation of tongue strength was conducted in a subset of the larger study, comprising the 8 LTC homes located in the province of Ontario. M3 participants were included in this portion of the study if they: 1) had a diet prescription that permitted them to drink thin liquids at mealtimes; 2) were alert and responsive; 3) were able to sit upright; and 4) were able to follow simple one-step directions. Residents were excluded if they were already receiving thickened liquids at meals or were unable to follow commands. Of the 160 Ontario residents included in the national study, the subset meeting the inclusion criteria for tongue strength measurement comprised 80 residents (20 male; mean age: 87.3 ± 7.04, range: 72-102). Measures of tongue strength were taken using the Iowa Oral Performance Instrument (IOPI). The IOPI is a handheld pressure bulb system that consists of a small air-filled bulb, which is placed in the mouth and squeezed between the tongue and the hard palate (see Figure 1). A strain gauge sensor inside
The device measures the amount of air displaced from the bulb in kilopascals (kPa). For this study, we used a custom LabView software program to register a digital pressure waveform from the analog output of the IOPI device at 250 Hz (see Figure 2). This enabled us to display a biofeedback screen view of the tongue-pressure waveform to the participant throughout data collection, and to extract detailed measures of tongue-pressure amplitude from the recorded signal. Maximum isometric tongue-pressures (MIPs) were recorded across a series of three bulb squeezes, with the bulb held in an anterior position, just behind the teeth (see Figure 3). Saliva swallows were recorded across a series of 3 cued tasks, with the bulb held in the same anterior position. Tongue-pressure tasks were cued with a 10-second rest between task repetitions. In total, 2 minutes were required to collect the tongue-pressure measures. A clean, individually wrapped, single-use tongue-pressure bulb was used for each participant, and discarded immediately after use.

Figure 1. The Iowa Oral Performance Instrument.

Figure 2. Sample of a waveform from maximum anterior isometric tongue pressures.
Data Analysis
Before analysis, the data were cleaned, noting any discrepancies, missing data and irregular data points. RAs and paper data collection forms were consulted to rectify errors when possible. Frequency statistics were calculated for the categorical variables (PG-SGA result; dysphagia status input variables; dysphagia status composite variable). Frequencies were then cross-tabulated to determine the co-occurrence of malnutrition and suspected dysphagia, and an odds-ratio was calculated to measure the association between these two variables.

Descriptive statistics (means and 95% confidence intervals) were calculated for continuous parameters (mealtime duration; food intake in calories). For the subset of residents from Ontario, descriptive statistics were also calculated for maximum anterior isometric tongue pressure (MIP), maximum saliva swallow pressure (MSP) and for swallow pressure expressed as a percent of MIP. Pearson correlations were run to determine whether tongue pressures varied as a function of age. Differences in mealtime duration and caloric intake were explored between participants classified with versus without suspected dysphagia using univariate analysis of variance (ANOVA). Univariate ANOVAs were also used to explore differences in MIPs and MSPs between participants classified with suspected dysphagia and those who were not. Additional post-hoc analyses of the tongue pressure data was performed between dichotomized subgroups of participants with MSPs ≤ or > the overall group mean MSP (normal; reduced swallow pressures), as well as performed for subgroups of participants who swallowed at ≤ or > 100% of their MIP. Differences between these two tongue strength subgroups were explored using univariate ANOVAs for the mealtime measures of mealtime duration, weight of food and drink intake, caloric intake, and calories consumed per minute. Frequencies were cross-tabulated.
to determine the co-occurrence of low swallow pressure and malnutrition, low swallow pressure and suspected dysphagia, as well as swallows >100% of MIP and malnutrition and swallows >100% of MIP and cognitive impairment.

**Results**

The data shown in Table 1 give details regarding the demographics, nutrition status, dysphagia risk factors, and measures of mealtime function for the participants enrolled in the current study. The data is displayed in three groups: all provinces, Ontario and Ontario subset. The ‘All Provinces’ column includes data for all four Canadian provinces involved in the study (New Brunswick, Ontario, Manitoba and Alberta. The ‘Ontario’ column includes data for all of the participants who were recruited from the province of Ontario, and their data is also included in the ‘All Provinces’ column. The ‘Ontario Subset’ column includes data for only the residents who were recruited from the province of Ontario to participate in the tongue strength measurements; these data are also a part of the ‘Ontario’ column. The ‘Ontario’ data is included simply as a means of comparison to the ‘Ontario Subset’ data.

**Nutritional Status**

As shown in Table 1, of the 639 residents included in the nationwide dataset, 638 had complete data for malnutrition. A total of 281 residents (44.0%) were found to be malnourished. Of these, 244 residents (38.2% of the total sample) were considered to be moderately malnourished as per the modified PG-SGA and 37 (5.8% of the total sample) were considered to be severely malnourished. Of the 80 residents in the Ontario subset who participated in the tongue strength measurement, 21 (26.3%) were considered to be malnourished, and of these residents 20 (28.1% of the Ontario subset) were moderately malnourished and 1 was severely malnourished.
Table 1. Demographics and health characteristics of study participants.

<table>
<thead>
<tr>
<th></th>
<th>All Provinces</th>
<th>Ontario</th>
<th>Ontario Subset</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>N</strong></td>
<td>639</td>
<td>160</td>
<td>80</td>
</tr>
<tr>
<td><strong>Age, mean (SD)</strong></td>
<td>86.8 (7.38)</td>
<td>87.3(7.04)</td>
<td>87.5(6.70)</td>
</tr>
<tr>
<td>**Gender, Men, n</td>
<td>%**</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td><strong>Malnutrition Total</strong></td>
<td>281</td>
<td>44.0</td>
<td>49</td>
</tr>
<tr>
<td><strong>Moderately malnourished</strong></td>
<td>244</td>
<td>38.2</td>
<td>45</td>
</tr>
<tr>
<td><strong>Severely malnourished</strong></td>
<td>37</td>
<td>5.8</td>
<td>4</td>
</tr>
<tr>
<td><strong>Suspected Dysphagia Total</strong></td>
<td>378</td>
<td>59.2</td>
<td>45</td>
</tr>
<tr>
<td><strong>Thickened liquids</strong></td>
<td>68</td>
<td>10.6</td>
<td>17</td>
</tr>
<tr>
<td><strong>Swallowing difficulties on STAND</strong></td>
<td>192</td>
<td>30.0</td>
<td>26</td>
</tr>
<tr>
<td><strong>Observed coughing at meals</strong></td>
<td>243</td>
<td>38.3</td>
<td>57</td>
</tr>
<tr>
<td><strong>Observed choking at meals</strong></td>
<td>19</td>
<td>3.0</td>
<td>12</td>
</tr>
<tr>
<td><strong>Difficulties on STAND + coughing/choking</strong></td>
<td>83</td>
<td>19.4</td>
<td>9</td>
</tr>
<tr>
<td><strong>Difficulties on STAND, no coughing/choking</strong></td>
<td>189</td>
<td>44.3</td>
<td>25</td>
</tr>
<tr>
<td><strong>Mealtime Duration (minutes), mean (SD)</strong></td>
<td>40.2(13.04)</td>
<td>39.3(11.31)</td>
<td>38.4(10.4)</td>
</tr>
<tr>
<td><strong>Caloric Intake, mean (SD)</strong></td>
<td>1575(413)</td>
<td>1639.6(391)</td>
<td>1631(411)</td>
</tr>
</tbody>
</table>

*a=n=638; b Suspected dysphagia total is the unique number of residents presenting with at least one of the conditions that make up the composite variable; c Only performed on n=427; d Only performed on n=89

Food Intake and Mealtime Duration
The nationwide average mealtime duration was 40.04 ± 17.4 minutes, and the average number of calories consumed at a meal was 1571 ± 421 calories, as can be seen in Table 1. In the Ontario subset, average MTD was 38.44 ± 10.43 minutes and average calorie consumption was 1631 ± 411 calories.

Dysphagia Status
As shown in Table 1, in the larger, nationwide data set, only 68 residents (10.6%) were found to have existing prescriptions for thickened fluids; of these, two-thirds (i.e., n = 46) were on nectar-thick fluids, 19 were receiving honey-thick liquids, and 3 residents were on the most restrictive modification, pudding-thick liquids. Signs of coughing during at least one observed meal were recorded for 243 residents (38.3% of the national sample) and choking was observed in 19 residents (3%). The STAND was completed in a total of 427 residents across the country and 192 of these residents (45%) showed signs of dysphagia. Closer inspection of the data revealed that almost equal numbers displayed signs of swallowing difficulty on the puree
swallow portion of the test (n = 78) and on the 90 mL water swallow portion (n = 79). As per the protocol for the STAND (Shephard, 2007), those who failed the puree swallow portion did not move on to the water swallow portion of the test. In total, 378 unique residents in the nationwide data set (i.e., 59.2%) met the composite criteria for being classified as having suspected dysphagia. Closer examination of the data also revealed that only 83 (19.4%) unique residents of the 427 residents who completed the STAND, displayed swallowing difficulties and either coughed or choked at mealtimes. Contrastingly, 189 residents (44.3%) showed signs of swallowing difficulty on the STAND but were not observed to cough or choke at meals.

In the Ontario subset, a single resident had a prescription for thickened liquids at meals. Two residents were observed to cough at least once during the meal observations, and one of these two residents was also observed to choke at least once. Signs of swallowing difficulty were observed during the STAND screening test in 23 residents (28.8%), of whom 17 failed the 90 mL water swallow portion of the screening test. In total, 25 residents of the 80 in the Ontario subset (31.3%) were classified as having suspected dysphagia. In this subset of residents, only 8 (10.0%) both coughed or choked at meals and showed signs of swallowing impairment on the STAND, whereas 23 residents (28.8%) displayed swallowing difficulties on only the STAND, without coughing or choking during meals.

**Association between Nutritional and Dysphagia Status**

Of the 279 residents in the nationwide dataset who were considered to be malnourished, 184 were also classified as having suspected dysphagia. Therefore, an overall co-occurrence rate of 29.0% was found for malnutrition and suspected dysphagia. Residents with suspected dysphagia had a higher prevalence and greater odds of malnutrition than those without dysphagia ($\chi^2(1) = 8.520$, $p<0.05$; odds ratio = 1.62, 95% confidence interval: 1.17-2.24).

**Association between Mealtime Measures, Intake and Dysphagia Status**

In the nationwide sample, average MTD was significantly longer in those classified with suspected dysphagia versus those without (F(1,363)=16.320, p<0.001; Cohen’s d = 0.4 [small]). LTC residents without suspected dysphagia took on average 38.65±12.51 minutes to eat, while those with suspected dysphagia took an average of 44.02±12.04 minutes to eat. However, the number of calories consumed did not change significantly based on dysphagia risk (F(1,363)=1.364, p=0.244).
Tongue-Strength

Complete tongue pressure data were only available for 64 of the 80 residents in the Ontario subset. Table 2 summarizes the means and 95% confidence intervals for the tongue-pressure parameters of interest, calculated based on three repetitions of each task obtained from each participant. There was little correlation between maximum swallowing pressures and age ($r^2=0.024$), and between maximum isometric pressures and age ($r^2=0.029$) (see Figures 4 and 5, respectively). On average, participants used 88.2% of their total tongue MIP range during saliva swallowing (95% CI: 79.8%-96.6%). As can be seen in Figure 6, swallowing pressures were notably lower in residents classified as having suspected dysphagia compared to those without (mean = 21.55 kPa, 95% CI: 16.98-26.13; versus mean = 28.21 kPa, 95% CI: 24.55-31.88), and this difference was statistically significant: $F(1,62)=5.152$, $p<0.05$; Cohen’s $d = 0.6$ [medium]. However, no difference in MIPs was found between those with and without suspected dysphagia ($F(1,78)=1.442$, $p=0.233$); those who were at risk for dysphagia had a MIP of 29.05 kPa (95% CI: 23.73-34.37), and those without signs of dysphagia had a mean MIP of 33 kPa (95% CI: 28.85-37.54). There were also no differences in swallow pressures as a percent of MIP for residents with and without suspected dysphagia ($F(1,62)=0.280$, $p=0.599$).

Table 2. Summary of tongue pressure parameters.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Mean</th>
<th>Lower confidence interval boundary</th>
<th>Upper confidence interval boundary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum tongue strength (kPa)</td>
<td>32.63(15.69)</td>
<td>28.71</td>
<td>36.55</td>
</tr>
<tr>
<td>Maximum saliva swallow pressure (kPa)</td>
<td>25.61(11.82)</td>
<td>22.66</td>
<td>28.56</td>
</tr>
</tbody>
</table>
Figure 4. Scatterplot displaying association between resident age and maximum swallow pressure.

$R^2$ Linear = 0.024
Figure 5. Scatterplot displaying association between resident age and maximum anterior isometric pressure.
Figure 6. Graph showing that swallowing pressures were significantly lower in residents classified as having suspected dysphagia compared to those without. No differences in maximum anterior isometric pressures were found between those with and without suspected dysphagia.

When the maximum swallow pressure parameter was dichotomized into a categorical variable (≤ vs > the overall mean MSP value of 25.61 kPa), 37 residents were classified as having low swallowing pressures. These individuals were more likely to be classified as having dysphagia than those with higher MSPs ($\chi^2(1)=5.56$, $p<0.05$; odds ratio: 3.694, 95% CI: 1.21-11.24). When swallow pressure status (low; high) was cross-tabulated against nutritional status, no differences were found in the frequency of malnutrition between groups ($\chi^2(1)=0.094$, $p=0.759$). Similarly, no significant differences were found between swallow pressure groups and caloric intake ($F(1,62)=0.10$, $p=0.921$). However, as seen in Figure 7, significant differences were found in mealtime duration between swallow pressure groups ($F(1,62)=6.65$, $p<0.05$; Cohen’s $d = 0.46$ [small]). Group differences in calories consumed per minute narrowly missed significance ($F(1,62)=3.932$, $p=0.05$).
The maximum swallow pressure parameter was also dichotomized into another categorical variable; mean swallow pressure greater than 100% of MIP and mean swallow pressure equal to or less than 100% of MIP. Twenty residents were classified as having swallow pressures that were greater than 100% of MIP. These participants were no more likely to be malnourished than those with swallow pressures less than 100% of MIP ($\chi^2(1)=0.190$, $p=0.663$), nor were they more likely to be more cognitively impaired ($\chi^2(1)=0.509$, $p=0.475$). However, significant differences were found between swallow pressure groups and amount of food and drink intake in grams ($F(1,62)=4.60$, $p<0.05$; Cohen’s $d = 0.61$ [medium]), MTD ($F(1,62)=4.65$, $p<0.05$; Cohen’s $d = 0.59$ [medium]), as well as mean calories per minute ($F(1,62)=5.54$, $p<0.05$; Cohen’s $d = 0.68$ [medium]). No significant differences were found between swallow pressure groups and resident age ($F(1,62)=0.15$, $p=0.70$) and caloric intake ($F(1,62)=1.11$, $p=0.30$).

Figure 7. Graph showing differences between mealtime duration for residents with swallow pressures above versus equal to or below the mean (25.6 kPa).
Residents with the combination of suspected dysphagia and low swallowing pressures had similar calorie consumption to those with higher swallow pressures and/or no signs of dysphagia (F(3,60)=0.799, p=0.500), and neither condition on its own resulted in significantly lower calorie consumption (swallowing pressures: F(1,60)=0.012, p=0.913; dysphagia risk: F(1,60)=1.396, p=.242). Residents with the combination of low swallowing pressures and suspected dysphagia took an average of 43.90 minutes to eat (95% CI: 39.48-48.31), which was significantly longer than those without dysphagia and/or with higher swallow pressures, who took an average of 33.77 minutes to eat (95% CI: 29.57-37.98) (F(3,60)=3.861, p<0.05; Cohen’s d = 0.59 [medium]). When compared separately, the group with reduced swallow pressures had significant longer mealtime durations, but this was not for residents who had signs of dysphagia (swallow pressures: F(1,60)=4.432, p<0.05, Cohen’s d = 0.46 [small]; dysphagia risk: F(1,60)=2.548, p=0.116). When calorie consumption and mealtime duration were combined, the number of calories consumed per minute was significantly lower in the group with both reduced swallow pressures and signs of dysphagia (F(3,60)=3.114, p<0.05; Cohen’s d = 0.35 [small]). Analyzed separately, neither swallow pressures nor dysphagia risk significantly influenced the mean number of calories consumed per minute (swallow pressure: F(1,60)=3.225, p=0.078; dysphagia risk: F(1,60)=1.658, p=0.203). Those with low swallow pressures and suspected dysphagia ate an average of 36.61 calories per minute (95% CI: 28.67-44.55) while those without dysphagia and/or higher swallow pressures ate an average of 51.75 calories per minute (95% CI: 44.20-59.30) (see Figure 8).
Discussion
These results illustrate that suspected dysphagia and malnutrition co-occur in the LTC setting, and that the presence of dysphagia significantly increases a LTC resident’s odds of becoming malnourished. Previous studies have suggested that malnutrition is a consequence of dysphagia, but this study establishes proof-of-principle regarding this association. We hypothesized that the co-occurrence of malnutrition would be greater than the range previously reported in a small pilot study of LTC residents (3% to 28%) (Namasivayam & Steele, 2015), however, we found the co-occurrence to only be slightly above previous reports, at 29%. It is important to note that the observed rate of co-occurrence may both under- or over-estimate the actual prevalence of
dysphagia, given that the composite dysphagia status parameter was based on screening rather than objective instrumental examination.

It was somewhat surprising to discover that a relatively small proportion of residents in LTC across the country were on a prescription for thickened fluids, given that this is described to be one of the most common ways to treat dysphagia (Logemann, 2003) and that a large proportion of residents were observed to be coughing at meals. If a thin liquid flows quickly through the mouth, it can spill into the pharynx prematurely and result in aspiration, which may trigger a cough response. Such circumstances may warrant the prescription of thickened fluids that flow more slowly through the oral cavity, and allow the swallowing mechanism more time to activate airway protection. Interestingly, almost equal numbers of residents failed the puree and 90 ml water swallowing portions of the STAND. In theory, purees are less likely to be aspirated because they move more slowly through the oral cavity and pharynx, similar to thickened liquids. However, thicker substances have been shown to cause more residue (Nicosia et al.). If residue remains in the pharynx post-swallow it may cause post-swallow aspiration, which could lead to choking. Purees like applesauce are generally considered one of the easier consistencies to consume, so if residents are displaying issues with this consistency, it is quite likely that they are also having difficulties swallowing other consistencies. The results of this study underscore the importance of screening for dysphagia as a means of preventing malnutrition, considering the large proportion of residents who were found to have suspected dysphagia (59.2% of the national sample). With appropriate training, dysphagia screening can be conducted by any of the registered health care professional staff in a LTC home, and will help prioritize residents who need to be referred to speech-language pathologists for more detailed assessment and intervention.

The maximum isometric tongue pressure values seen in the current study are similar to those previously reported for healthy elderly adults over the age of 80. Vanderwegen and colleagues reported that men over the age of 80 have mean anterior MIPs of 33.70 kPa and women over the age of 80 have mean anterior MIPs of about 28.11 kPa (Vanderwegen, Guns, Van Nuffelen, Elen, & De Bodt, 2013). We found mean anterior MIPs of 32.63 kPa (95% CI: 28.71-36.55) for a group of both men and women. By contrast, the saliva swallow pressures measured in the current study fell below those previously reported in the literature. Nicosia (Nicosia et al., 2000) and Robbins (Robbins, Levine, Wood, Roecker, & Luschei, 1995) both
performed similar studies looking at tongue strength during saliva swallowing with the IOPI but presented their data in graphic form without exact numbers, so results cannot be compared. Youmans and Stierwalt (Youmans & Stierwalt, 2006) also measured swallowing pressures but used a bolus rather than saliva. They found that older adults aged 60-79 had a mean swallow pressure of 29.6 kPa with a thin liquid bolus, compared to our group who had a mean saliva swallow pressure of 25.61 kPa (95% CI: 22.66-28.56). Because of the differences between studies, including both subject attributes and materials swallowed, it is difficult to compare these numbers. The lower pressures observed in this study may be attributable to the increased age and vulnerability of the LTC population. Furthermore, increased prevalence of malnutrition in LTC, which may lead to frailty and sarcopenia, could plausibly contribute to weaker tongue pressures. Further investigation is warranted regarding pressures generated during swallowing in the elderly.

Youmans and Stierwalt (Youmans & Stierwalt, 2006) also reported swallow pressures as a percentage of MIP. They found that the older adults in their sample used 53.8% of their MIP-range to swallow. Robbins and colleagues (Robbins et al., 1995) have also studied this parameter, reporting that older adults generally used 45.9% of their MIP-range to swallow. The results in our study are considerably higher, with elderly adults in LTC using 88.2% of their MIP-range to swallow. As previously acknowledged, the studies differed in many ways, including the fact that both prior studies used a bolus while measuring swallowing pressures, rather than saliva. It is also interesting to note that approximately one third of the residents were using over 100% of their MIP-range to swallow, but this was unrelated to cognitive impairment. Our study does suggest that functional reserve, i.e., the difference between MIPs and MSPs (Steele et al., 2013), is significantly reduced in the LTC population. Reductions in functional reserve have been argued to have possible clinical implications, putting patients at greater risk of developing functional swallow impairments, particularly in the case of decompensation (Fei et al., 2013; Nicosia et al., 2000). However, given that swallow pressures expressed as a percentage of MIPs had no bearing on suspected dysphagia within the current study and many residents had no functional reserve at all (i.e. when swallow pressures were greater than 100% of MIP), the clinical significance of functional reserve remains in question.

Initially, we hypothesized that the current study would show results similar to a previous pilot study performed in 12 residents from a single LTC home, which showed that residents with
MIPs below 28 kPa took significantly longer to eat, ate less and displayed more mealtime difficulties than those who had MIPs above 28 kPa (Namasivayam et al., 2016). The current study did not corroborate these results; rather, differences in MIPs appeared to be less important than differences in swallow pressures. We found that residents were using a larger proportion of their MIP-range in order to produce a swallow, and swallow pressures were more predictive of both dysphagia risk and mealtime performance (mealtime duration and number of calories consumed per minute). The results suggest that a reduction in swallow pressures generated by the tongue puts residents at a significantly increased risk for dysphagia. Suspected dysphagia, in turn, increases the risk of malnutrition, as seen in the 29% co-occurrence of malnutrition and suspected dysphagia in our LTC sample. When low swallow pressures were combined with dysphagia risk, mealtime outcomes were also affected, with residents tending to take longer to eat and consuming fewer calories per minute. This increase in meal duration and decrease in caloric intake could reflect fatigue and reduced endurance. Previous research has shown that the act of eating a meal may be sufficient to cause fatigue and reduced post-meal measures of tongue strength in healthy elderly individuals (Kays et al., 2010). These results may be exacerbated in a more vulnerable population, such as the elderly residing in LTC. The findings of the current study point to the possibility that interventions targeting improved tongue strength in LTC may reduce the risk of dysphagia, which in turn may help to mitigate malnutrition in this population.

Limitations
There are several limitations to note for the current study. First, it is important to recognize that data analysis only focused on the data for participants recruited from all four provinces involved in the study, as well as the subset of LTC residents from Ontario who participated in the measurements of tongue strength. Data from all of the participants from Ontario, which included those who did not participate in the tongue strength measurements, were not analyzed. It is also important to note that the presence of dysphagia was determined based on a screening protocol rather than formal evaluation. The sensitivity of the STAND has been reported to be high for detecting both dysphagia and aspiration but the specificity of the screening tool was moderate; consequently, there is a chance that the number of residents considered to be at risk for dysphagia in this study was over-estimated. Additionally, an existing prescription for thickened
fluids was accepted as a sign of dysphagia in this study. There are, however, several reasons why residents may be on thickened liquids, including poor oral health, so this may not be the best way to capture dysphagia risk. Swallowing impairment is also not the only reason why someone may cough or choke at a meal. A broad array of factors that can influence mealtime performance, including distractibility, availability of eating assistance and palatability of the food (Namasivayam et al., 2016), could also have influenced the occurrence of coughing and choking seen at mealtimes, leading to possible inflation of estimated dysphagia prevalence.

Another limitation of the study is the fact that medications were not considered; several medications are known to alter appetite and this may have influenced caloric intake, lethargy, and mealtime duration. Measures of caloric intake may have also been confounded by imprecise estimates of food and drink intake between meals by RAs and LTC staff. Measures of mealtime function are also difficult to compare across facilities with different menus; in this study it was not guaranteed that all of the residents were eating the same foods at each meal.

A further limitation of this study is the fact that only anterior maximum isometric tongue pressures were measured, rather than also looking at posterior maximum isometric tongue pressures. The anterior tongue is used for formation, placement and manipulation of the bolus in the oral cavity, whereas the posterior tongue is primarily responsible for containment of the bolus in the oral cavity and propulsion into the pharynx. Given the crucial role of the posterior tongue in the swallowing process, it would have been ideal to also assess the strength of the posterior tongue. Through this measurement we may better understand whether weakness in the anterior or posterior tongue contributes more to mealtime difficulties, or whether both play an equal role. It would have also been beneficial to measure swallowing pressures using a bolus rather than saliva in order to draw comparisons to previous studies in the literature. However, it is particularly challenging to manage both a bolus and the IOPI bulb in the mouth at the same time; given the advanced age and prevalence of dementia in this sample, we decided to stick with the safer and less challenging option of measuring swallowing pressures with saliva.

**Conclusion**
The findings of our study have several significant implications. This is the first large study to quantify both malnutrition and risk of dysphagia among elderly residents of LTC, many of whom had dementia. We found that malnutrition occurs in 44% of LTC residents, risk of
dysphagia occurs in 59% of residents, and the conditions co-occur in approximately 29% of the LTC population. We were also able to show that for residents living in LTC, having low swallow pressures significantly increases their odds of having dysphagia and in turn, if they present with signs or symptoms of dysphagia, their odds of becoming malnourished increase significantly. Moreover, those with low swallow pressures take significantly longer to eat and consume fewer calories per minute compared to those who do not have low swallow pressures. With these findings we can move forward to explore feasible methods to improve tongue strength and reduce the risk of dysphagia in LTC. Further research is also warranted to confirm the prevalence of dysphagia in LTC using objective instrumental examinations, rather than screening, and to confirm how the presence of dysphagia affects nutrition.
References


Chapter 5
Tongue Strengthening to Improve Mealtime Outcomes in Long Term Care: A Proof-of-Principle Study


Introduction
Advancing age is associated with major changes in body composition including sarcopenia in the limb musculature, which is an age-related loss in skeletal muscle (Cohn et al., 1980). The consequences of sarcopenia are decreased strength and aerobic capacity, leading to reduced functional capacity (Bassey, Morgan, Dallosso, & Ebrahim, 1989). Physical exercise and resistance training of the limb muscles have been shown to yield large increases in strength in the elderly, minimizing or reversing physical frailty amongst very old individuals living in long term care (LTC) (Evans, 1997). Age-related diminishment in strength, mobility and endurance is also evident in the tongue (Nicosia et al., 2000; Robbins, Levine, Wood, Roecker, & Luschei, 1995). Research has shown that objective measures of tongue pressure are associated both with oral phase swallowing impairments (Clark, Henson, Barber, Stierwalt, & Sherrill, 2003) and with aspiration (entry of foreign material into the airway during swallowing) (Butler et al., 2011). In this paper, we describe the results of a preliminary study exploring the benefits of a tongue-pressure training intervention to address tongue weakness among seniors residing in LTC care.

According to the Alzheimer’s Society of Canada (Alzheimer’s Society, 2012), approximately 747,000 Canadians currently have some type of dementia and more than 200,000 of these people reside in LTC. Dysphagia (swallowing impairment) is a known comorbidity of those with dementia (Easterling & Robbins, 2008) and when present, dysphagia predisposes individuals with dementia to dehydration, malnutrition, weight loss, and aspiration pneumonia (Hudson, Daubert, & Mills, 2000; Mendez, Friedman, & Castell, 1991; Mion, McDowell, & Heaney, 1994). Studies have shown that tongue-pressure training is an effective intervention for
reduced tongue strength in healthy individuals (Robbins et al., 2007), those with dysphagia after stroke (Steele et al., 2016), and those with dysphagia after acquired brain injury (Steele et al., 2013). However, tongue pressure training has not been explored in the LTC population, or in individuals in the early stages of dementia. Associations have been found between reduced tongue strength in LTC residents and increased prevalence of mealtime difficulties, longer meal durations and reduced food consumption (Namasivayam, Steele, & Keller, 2016). Given these relationships, interventions that are effective for improving tongue strength may also help to reduce the risk for dysphagia in LTC, promote better mealtime function and improve nutritional intake. In the present study we sought to determine the feasibility and effectiveness of an 8-week tongue strengthening intervention protocol for seniors with cognitive impairment in the LTC setting. We hypothesized that adults enrolled in the study would demonstrate significant improvements in tongue strength as a result of treatment. We were further interested to determine whether gains in tongue strength would be associated with improvements in functional mealtime measures, such as mealtime duration, amount of food consumed and number of observed mealtime difficulties.

Methods
This study received human subjects approval from the local institutional research ethics board.

Participants
A sample of eight residents (2 male; 6 female; mean age of 91 years; range 84-99) were enrolled in the study at a LTC facility in Toronto, Canada. Potential participants were identified and initially approached by care staff, based the following inclusion criteria: (1) over the age of 65; (2) required at least 2 hours per day of nursing care due to dependence in activities of daily living (e.g. bathing); (3) able to follow simple, three-step directions; and (4) able to commit to 8 weeks of an intervention, scheduled twice per week. Pre-existing dysphagia was not an inclusion criterion since we wanted to establish proof-of-principle in a group of residents who had not yet begun to demonstrate signs or symptoms of swallowing impairment. Residents were excluded if they: (1) were medically unstable (i.e., acute care hospitalization within the month prior to enrollment); (2) were on a short term admission (e.g. respite care); (3) required tube-feeding; (4) were receiving palliative care; and/or (5) had advanced directives that excluded
them from research. Once a potential participant was identified an intake session was scheduled, during which maximum isometric tongue pressures (MIPs) were measured to confirm the presence of tongue weakness. To be included in the study, residents had to demonstrate a MIP less than 40 kilopascals (kPa) on at least 3 out of 10 baseline measures, with half of these collected at the anterior palate and half at the posterior palate. Once eligibility was confirmed, written consent to participate was obtained from the participant or their substitute decision maker. Age, sex, score on the Cognitive Performance Scale (CPS) and major medical diagnoses were collected from the health records of each participant at the point of intake. The CPS combines information on memory impairment, level of consciousness and executive function, with scores ranging from 0 (intact) to 6 (very severe impairment) (Morris et al., 1994). The CPS has been shown to be highly correlated with the Mini Mental State Examination (Hartmaier et al., 1995).

**Measures of Tongue Strength**
The Iowa Oral Performance Instrument [IOPI] (www.iopimedical.com) was used both for tongue-pressure measurement and for monitoring tongue-pressure values during treatment sessions. The IOPI is a handheld manometry device, with a teaspoon-sized, air-filled bulb, which is placed on the upper surface of the tongue (Robbins et al., 2005) (see Figure 1). Anterior placement means that the flat front end of the bulb is positioned just behind the teeth. Posterior placement involves aligning the flat front end of the bulb with the anterior edge of the first molar tooth (LaPointe, Gingrich, Stierwalt, & Hageman, 2012). When compressed between the tongue and palate, the amount of displaced air is registered in kilopascals (kPa) on the device monitor. Participants were given feedback regarding their MIPs throughout their baseline intake measurement to encourage them to try to generate the strongest pressures possible.
Measures of Mealtime Function

Measurements of mealtime function were collected through repeated meal observations. A single set of mealtime observations involved a research assistant (RA) observing the resident at two regularly scheduled meals (one lunch and one dinner) in the facility dining room. Both meal observations were scheduled in the same week and the RAs were blinded to any information regarding the resident’s tongue strength. RAs entered the dining area before the scheduled start of the meal and remained there until after the resident had completed their meal. They sat in a corner away from the residents so as not to distract them, but positioned themselves in order to be able to clearly see each resident they were observing. There was no interaction between the RAs and the residents.

Mealtime duration was recorded as the interval of time when the resident was at their table with food and/or fluid in front of them for consumption. The end of meal was captured as the time when the resident left the dining area and did not return, or when no food/fluid remained in front of the resident. If the resident left the dining room briefly but then returned to their table to continue eating, or if the resident stopped eating for a brief period of time, this time was subtracted from mealtime duration in order to accurately capture the time spent eating. The amount of food eaten was determined by weighing each resident’s food tray with a kitchen scale prior to the resident beginning their meal and after the resident had finished their meal. Reference weights for all service-ware were collected at the beginning of the study so that the true weight of consumed food and liquid could be determined.
In addition to observing meal duration and measuring the amount of food and drink intake, the RAs completed the Edinburgh Feeding Evaluation for Dementia (EdFED) questionnaire for each meal observation. The EdFED is a validated scale that documents the occurrence of ten different types of mealtime eating difficulties (Watson, 1994), with each problem scored as occurring never (1), sometimes (2), or often (3). A list of the questions can be found in Table 1. An overall EdFED score of greater than 10 is considered sufficient to indicate that the resident has mealtime difficulties. As this tool does not directly capture signs of swallowing difficulty, two additional questions were added, focusing on signs of swallowing difficulty (Does the resident cough during the meal? Does the resident choke during the meal?). These additional items were scored in a manner consistent with the EdFED.

Table 1. EdFED and additional questions to evaluate mealtime difficulties.

<table>
<thead>
<tr>
<th>EdFED Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Does the resident require close supervision while feeding/eating?</td>
</tr>
<tr>
<td>b. Does the resident require physical help while feeding/eating?</td>
</tr>
<tr>
<td>c. Is there spillage while feeding/eating?</td>
</tr>
<tr>
<td>d. Does the resident tend to leave food on the plate at the end of the meal?</td>
</tr>
<tr>
<td>e. Does the resident ever refuse to eat?</td>
</tr>
<tr>
<td>f. Does the resident ever spit out his food?</td>
</tr>
<tr>
<td>g. Is there spillage of food out of the mouth?</td>
</tr>
<tr>
<td>h. Does the resident ever turn his head away while being fed?</td>
</tr>
<tr>
<td>i. Does the resident ever refuse to open his mouth?</td>
</tr>
<tr>
<td>j. Does the resident ever refuse to swallow?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Additional Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Does the resident cough during the meal?</td>
</tr>
<tr>
<td>b. Does the resident choke during the meal?</td>
</tr>
</tbody>
</table>
Study Design
The 8 residents who were enrolled in the study came from two different units in the long-term care facility. For ease of scheduling, the sample was divided into two groups based on their unit of origin: one unit was randomly selected to be an early treatment group (Group A), while the other was assigned to be the later group (Group B). In addition to measuring changes in tongue strength across the 8-week intervention, a multiple baselines design was used to monitor any associated changes in mealtime function. As shown in Figure 2, three sets of meal observations (a total of 6 meals) were completed over a 6-week baseline phase for participants in Group A, with each set of observations scheduled approximately two weeks apart. For participants in Group B, these same meal observations were completed, but the baseline phase continued for a further 4 weeks, yielding a total of 5 sets of baseline mealtime observations (10 meals). For both groups, the intervention phase comprised 16 treatment sessions, scheduled twice per week over 8 weeks. Group A reached the end of intervention 4 weeks prior to Group B. A final set of 2 mealtime observations was completed for each group in the week following the end of treatment.
Tongue Strength Training Intervention

Individual tongue strengthening intervention sessions (20-40 minutes in length) were conducted by two licensed speech-language pathologists, who were blinded to the mealtime observation data. All participants received the same tongue pressure strength and accuracy training (TPSAT) program. This protocol was chosen based on evidence from two recent studies by Steele et al. (Steele et al., 2013; Steele et al., 2016), who found the protocol to be effective for improving tongue strength in adults with dysphagia following acquired brain injury or stroke. As shown in Figure 3, the TPSAT protocol is divided evenly between tasks focusing on the anterior tongue and the posterior tongue. Exercise for both parts of the tongue is considered important due to the different functions played by these regions of the tongue in swallowing. Specifically, the anterior tongue is used for formation, placement and manipulation of the bolus in the oral cavity during swallowing, while the posterior tongue is responsible for containment of the bolus in the
oral cavity and propulsion into the pharynx (Hiemae & Palmer, 1999). In the TPSAT protocol, half of the exercises in each bulb position comprised isometric pressure tasks, for which the participant was instructed to press the bulb to the roof of their mouth as hard as possible. The remaining exercises consisted of accuracy tasks, where the participant was instructed to try to generate precise pressures in either the anterior or posterior bulb location. The target amplitudes for the accuracy task were randomly selected by a computer program, falling between 25% and 85% of the participant’s maximum pressure range, measured during the first five isometric strength exercises in the session for each bulb location. In order to provide visual biofeedback to all participants during treatment sessions, the pressure signal was exported from the data output port on the IOPI device, and displayed as a waveform on a computer screen (see Figure 4). Positive reinforcement was also provided directly to the participant by the clinician after each attempt by telling them the pressure value registered on the IOPI device and providing encouraging comments, such as “Well done! Your peak pressure was X, and close to the target” or “That was a nice try. Your peak pressure was X which is about half of the value we are hoping for. See if you can get closer on the next try.” There was no home practice component outside of the face to face therapy sessions with the speech-language pathologist.
Figure 3. Flow-chart of a tongue-pressure strength and accuracy training session

Figure 4. Waveform data and biofeedback from tongue strengthening protocol provided to participants.
Analysis

Tongue Strength Measures
To determine whether tongue strength improvements were seen in this study, we compared MIP values for the first 3 and final 3 treatment sessions. The MIP data from all participants across these 6 sessions was initially pooled in order to identify any extreme outliers (i.e. values exceeding the third quartile by a full interquartile range) and remove these from the data. For the anterior MIPs, outliers were considered to be any values over 64 kPa, and outliers for the posterior MIPs were considered to be any values over 61 kPa. A total of six data points were removed from the anterior MIP data, and none were removed from the posterior MIP data. The outliers were replaced by missing values.

Within-participant changes in tongue strength were monitored across the entire course of treatment using a control chart method, as illustrated in Figures 5 and 6. For each treatment session, mean values for either the anterior or posterior strength tasks were plotted, with standard deviations represented by error bars. The first three data points (intake and first two treatment sessions) constituted the baseline reference range to which subsequent data were compared. An a priori threshold for identifying improvements in tongue strength was established, based on a medium effect-size calculation (Cohen’s $d = 0.5$). Cohen’s $d$ can be interpreted as showing a small effect size for values of $<0.5$, medium effect size for values of $0.5–0.8$, and large effect size for values $>0.8$ (Dunlap, Cortina, Vaslow, & Burke, 1996; Joe & Heather, 2003). In order to conclude that an improvement in MIP values had occurred, we required evidence of three or more consecutive data points falling above the medium effect size threshold and the subsequent points remaining there.

Groupwise investigations of differences in tongue strength were conducted in SPSS 24.0 using an alpha criterion of $p<0.05$. Repeated measures analyses of variance (ANOVA) with a between-participants factor of Group (A vs B) and a within-participants factor of baseline observation number (#) were run for measures of tongue strength and all mealtime outcomes. Given the absence of group differences at baseline, differences in tongue strength as a function of treatment were explored for each tongue pressure parameter between the first three sessions and the final three sessions using univariate repeated measures ANOVA with a repeated factor
of time point (baseline vs. outcome). Significant effects were further explored with post hoc analyses of effect size using Cohen’s $d$.

**Measures of Mealtime Function**

Single-subject methods were used to explore baseline and post-treatment data for all measures of mealtime function. Means and standard deviations for EdFED scores, mealtime durations and amount of food consumed (in grams and percentage of food served) were calculated from the data collected from the 6 or 10 baseline observations (depending on the group) and the two post-treatment observations. The amount of food and drink consumed at each mealtime observation was determined by subtracting the post-meal weight of the food tray from the corresponding pre-meal tray weight (i.e. pre-meal food tray – post-meal food tray = grams of food and drink consumed). The percentage of food and drink consumed was calculated by taking the pre-meal and post-meal weights of the food tray and subtracting from these the weights of all service-ware in order to determine the true weight of the food and drink offered to and consumed by the resident. The weight of food and drink consumed was then divided by the weight of the food and drink offered and multiplied by 100 in order to yield the percentage intake at each meal (i.e. (grams of food and drink consumed/grams of food and drink offered) x 100 = percentage of food and drink consumed). EdFED scores were derived by tallying the scores received on each item, and mealtime durations were calculated as total mealtime minus any prolonged periods of distractions.

**Results**

Table 2 provides the demographic details for all the participants who were enrolled an average of 2.9 years after admission into the LTC home. Three residents had a score of 1 on the CPS indicating that their cognitive performance was borderline intact. Two other residents had a CPS score of 3, indicating their cognition was moderately impaired, while the remaining two participants had a score of 4, indicating that their cognition was moderately to severely impaired. Seven of the eight residents enrolled were drinking thin liquids at all meals, and 5 of the 8 were eating all types of solid foods. Three residents were on minced solid diets, and these resident coincidentally also had CPS scores of either 3 or 4.
Table 2. Participant demographics.

<table>
<thead>
<tr>
<th>Participant Number</th>
<th>Sex</th>
<th>Age</th>
<th>CPS Score</th>
<th>Presence of Dentures</th>
<th>Diet</th>
<th>Major Medical Diagnoses</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>F</td>
<td>85</td>
<td>3</td>
<td>N</td>
<td>Regular liquids, minced solids</td>
<td>Congestive heart failure, dementia, cardiovascular disease, hemiplegia left side</td>
</tr>
<tr>
<td>2</td>
<td>M</td>
<td>95</td>
<td>4</td>
<td>N</td>
<td>Regular liquids, minced solids</td>
<td>Aphasia, atherosclerotic heart disease, schizophrenia</td>
</tr>
<tr>
<td>3</td>
<td>F</td>
<td>93</td>
<td>1</td>
<td>N</td>
<td>Regular liquids and solids</td>
<td>Peripheral vascular disease, spastic hemiplegia</td>
</tr>
<tr>
<td>4</td>
<td>F</td>
<td>91</td>
<td>3</td>
<td>Y</td>
<td>Regular liquids and solids</td>
<td>Dementia, congestive heart failure</td>
</tr>
<tr>
<td>5</td>
<td>M</td>
<td>86</td>
<td>4</td>
<td>Y</td>
<td>Honey-thick liquids, minced solids</td>
<td>Parkinson's disease, aphasia, cardiovascular disease</td>
</tr>
<tr>
<td>6</td>
<td>F</td>
<td>99</td>
<td>1</td>
<td>N</td>
<td>Regular liquids and solids</td>
<td>Congestive heart failure</td>
</tr>
<tr>
<td>7</td>
<td>F</td>
<td>84</td>
<td>1</td>
<td>N</td>
<td>Regular liquids and solids</td>
<td>Dementia, COPD</td>
</tr>
<tr>
<td>8</td>
<td>F</td>
<td>96</td>
<td>3</td>
<td>Y</td>
<td>Regular liquids and solids</td>
<td>Dementia</td>
</tr>
</tbody>
</table>

Complete data were available for seven participants who completed all 16 treatment sessions and meal observations. One participant became ill and was put on contact precautions after her first intervention session; she declined to resume the intervention once her health improved. There were no significant group differences at baseline for any of the parameters measured: anterior MIPs (F(1,5)=1.958, p=0.221), posterior MIPs (F(1,5)=2.733, p=0.159), mealtime duration (F(1,5)=1.61, p=0.330), EdFED score (F(1,5)=0.143, p=0.721), grams of food consumed (F(1,5)=0.013, p=0.912), and percentage of food intake (F(1,5)=1.812, p=0.236). Moreover, there was good stability across repeated baseline meal observations, regardless of group, for all mealtime measures: mealtime duration (F(9,31)=0.857, p=0.572); EdFED score (F(9,31)=1.276, p=0.288); percentage of intake (F(9,31)=1.078, p=0.406); grams
consumed (F(9,31)=1.064, p=0.415). Based on these results, there was no reason to expect that the two participant groups would have different outcomes post-treatment.

**Tongue Strength**

As can be seen in control charts of the single subject data (Figures 5 and 6), six of the seven residents who completed the tongue strength training intervention showed marked improvements in both anterior and posterior tongue strength. These six participants all achieved or surpassed the a priori definition of improvement, i.e. displaying values that were stronger than those seen across the first three measurements by a value equal to or greater than a medium effect-size threshold. At baseline, anterior MIPs for the entire sample had a mean value of 23 kPa (95% confidence interval: 15-31 kPa). Outcome anterior MIP measures (based on the last three intervention sessions) increased significantly to a mean value of 44 kPa (95% CI: 40-48 kPa); [F(1,6) = 223.80, p<0.001; Cohen’s d = 2.31 (large)]. Similarly, posterior MIPs improved from a baseline mean value of 19 kPa (95% CI: 12-27 kPa) to an outcome mean of 38 kPa (95% CI: 30-46 kPa); [F(1,6) = 154.30, p<0.001; Cohen’s d = 1.81 (large)]. Post hoc analyses showed average gains of 21 kPa for anterior pressures (95% CI: 11-30 kPa) and 19 kPa in the posterior position (95% CI: 6-31 kPa).
Figure 5. Anterior tongue maximum isometric pressures from baseline to the end of intervention for Participants 1 through 7.
Figure 6. Posterior tongue maximum isometric measures from baseline to the end of intervention for Participants 1-7.
Mealtime Outcomes

Table 3 displays each participant’s mean baseline and post-treatment data for mealtime duration, grams of food and drink intake, percentage of food and drink consumed, and the occurrence of mealtime difficulties. A single participant (Participant 3) showed improvement across all four measures, even though she made marginal improvements in tongue strength. Four of the seven participants displayed shorter mealtime duration post-treatment, but most of these improvements were very small; Participant 1 improved by only 0.44 minutes, Participant 3 by 0.56 minutes, Participant 6 by 0.67 minutes, and Participant 7 by 2.36 minutes. The remaining three residents actually displayed longer post-treatment mealtime duration anywhere from about one to almost five minutes, but these variations were all well within the standard deviation of the baseline measures. The pre-treatment group mean mealtime duration was 17.76 ± 8.52 minutes, and the post-treatment group mean mealtime duration was 18.75 ± 7.26 minutes.

Table 3. Mean mealtime duration (MTD), percentage of food intake and EdFED scores for all participants who participated in the intervention. All values have been rounded to the nearest integer.

<table>
<thead>
<tr>
<th>Participant Number</th>
<th>MTD (min)</th>
<th>Grams Consumed</th>
<th>% of Food Intake</th>
<th>EdFED Score</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre-tx</td>
<td>Post-tx</td>
<td>Pre-tx</td>
<td>Post-tx</td>
</tr>
<tr>
<td>1</td>
<td>13(4)</td>
<td>12(3)</td>
<td>680(50)</td>
<td>406(148)</td>
</tr>
<tr>
<td>2</td>
<td>25(7)</td>
<td>27(7)</td>
<td>610(107)</td>
<td>250(121)</td>
</tr>
<tr>
<td>3</td>
<td>15(6)</td>
<td>15(7)</td>
<td>446(79)</td>
<td>579(214)</td>
</tr>
<tr>
<td>4</td>
<td>9(3)</td>
<td>10(2)</td>
<td>513(89)</td>
<td>560(129)</td>
</tr>
<tr>
<td>5</td>
<td>15(3)</td>
<td>19(0)</td>
<td>478(74)</td>
<td>403(37)</td>
</tr>
<tr>
<td>6</td>
<td>21(7)</td>
<td>21(4)</td>
<td>369(79)</td>
<td>364(146)</td>
</tr>
<tr>
<td>7</td>
<td>30(11)</td>
<td>27(4)</td>
<td>531(128)</td>
<td>396(111)</td>
</tr>
</tbody>
</table>

The pre-treatment group mean percentage of intake, based on amount of food and drink provided, was 60.41% ± 15.06%, and post-treatment the mean dropped slightly to 56.64% ± 14.57%. Grams of food and drink consumed were 498.66 ± 124.41 grams pre-treatment and...
422.34 ± 149.34 grams post-treatment. Inspection of the individual participant data showed increased post-treatment food intake compared to baseline for three residents. The greatest increase was seen in Participant 3, who consumed 133.43 grams more food and drink post-treatment than at baseline (a 22% increase in intake from baseline). Five residents showed post-treatment decreases in amount of food consumed, from 4.69 grams to 359.9 grams (4% to 35% decrease in food and drink intake from baseline).

The pre-treatment median EdFED score, without the two additional questions regarding coughing and choking, for all participants was 14, suggesting that all 8 residents met the EdFED criterion for being classified as experiencing mealtime difficulties. The most common score at baseline was 13 (range: 11-17). Post-treatment, the median EdFED score dropped to 13, with a score of 12 occurring most often (range: 11-17). Only four residents showed improvements in EdFED scores post-treatment, but these changes were marginal; Participant 3 and 7 showed the most improvement but only increased by an average of 1 point. In analyzing the specific items on the EdFED in more detail, it became clear that none of the residents were ever reported to turn their head away while being fed, to refuse to open their mouths or to refuse to swallow. Five residents were observed coughing at meals and four residents were observed choking at meals. None of the participants were observed to cough or choke at every meal across the baseline and outcome observations. Four residents were consistently observed to have spillage from the mouth while eating or drinking, and three residents were consistently observed to leave food on the plate at the end of the meal, both at baseline and pre-treatment. None of the consistently observed mealtime difficulties for each resident were completely resolved post-treatment; that is to say no clear functional mealtime improvements were made, as measured by the EdFED.

**Discussion**

This study provides proof-of-principle that tongue-pressure resistance training is effective for improving tongue strength among elderly residents living in LTC, four of whom had dementia (as per their CPS scores). This finding is similar to the results of previous studies in healthy seniors, stroke patients, and individuals with acquired brain injury (Robbins et al., 2005; Robbins et al., 2007; Steele et al., 2013; Steele et al., 2016; Yeates, Molfenter, & Steele, 2008).
Compared to these other studies, a greater magnitude of increased tongue strength was observed in the present study, regardless of bulb position. The average gain of 21 kPa anteriorly and 19 kPa posteriorly is similar to the average strength increase of 20 kPa reported by Steele and colleagues in a tongue pressure training study for patients after stroke (Steele et al., 2016), but slightly less than the gains reported by Robbins and colleagues for post-stroke patients (Robbins et al., 2007). Not surprisingly, the mean baseline pressures of the residents in the current study were well below the reported norms for healthy, older adults, which ranged from 27 kPa (Vanderwegen, Guns, Van Nuffelen, Elen, & De Bodt, 2013) to 69 kPa (Solomon, Robin, & Luschei, 2000). However, the significant increases in tongue strength seen over the course of this study increased the mean values for tongue strength post-treatment to measurements above the means and confidence intervals reported by Vanderwegen and colleagues for adults over the age of 80 (Vanderwegen et al., 2013). The extremely low initial tongue strength values seen in this sample may also suggest the presence of sarcopenia as hypothesized by Nicosia and colleagues (Nicosia et al., 2000), but the tongue strengthening intervention could possibly reverse this, similar to what has been done with strengthening interventions in the limb musculature (Evans, 1997).

Despite large improvements in tongue strength, this study failed to show evidence of associated improvements in measures of mealtime function such as mealtime duration, food and drink intake, or the occurrence of mealtime difficulties. These findings suggest that these functional mealtime measures are not directly sensitive to changes in tongue strength. Rather, these data are consistent with the idea that poor food intake in older adults is multifactorial and becomes a greater problem in the later stages of dementia (Keller et al., 2016). It is important to keep in mind that the residents in this proof-of-principle study were not enrolled on the basis of pre-existing dysphagia or swallowing complaints. Residents were enrolled based on evidence of reduced tongue strength to see whether tongue strengthening was feasible in this population. The results confirm that tongue pressure training can be used to improve tongue strength in this population.

The investigation of associated changes in mealtime outcomes was motivated by previous reports of correlations between low tongue strength and functional mealtime outcomes (Namasivayam et al., 2016). The small sample and limited number of post-treatment meal
observations in this study may have hindered our ability to detect changes in mealtime outcomes. Changing only one factor (i.e. tongue strength) in a small number of individuals proved to be insufficient, and likely under-powered, to demonstrate an impact on measures of mealtime function, and suggests that other factors are also likely to have been at play. Recent studies of nutritional intake in seniors residing in LTC suggests that a wide array of factors affect food intake, including distractibility, availability of eating assistance, depression, and lack of food choice (Keller et al., 2016). These were not factors that were controlled in the current study.

If tongue strength is indeed related to swallowing function in elderly individuals in LTC, it would have been reasonable to expect that the improved tongue strength seen in this study might have resulted in observations of less coughing and choking at mealtimes. There were, however, no notable improvements, or changes in these parameters between baseline and post-treatment observations. It is also possible that participants experienced improvements in their swallowing function that were not detected based on the measures selected for the present study. Using videofluoroscopy, Steele et al. (Steele et al., 2016) observed that tongue pressure resistance training was effective for reducing post-swallow residue in the pharynx. Similarly, another study employing videofluoroscopy (Yeates et al., 2008) showed improvement in oral bolus control, in the form of reduced spillage of the bolus into the pharynx prior to the initiation of the swallow. This sort of improvement has the potential to reduce the occurrence of aspiration and its sequelae, based on the findings of a recent study performed by Rogus-Pulia and colleagues that reported a 67% reduction in pneumonia diagnoses after older adults completed an 8-week tongue strengthening intervention (Rogus-Pulia et al., 2016). Measurement of physiological swallowing outcomes was not explored in the current project, but would be interesting to include in future studies of tongue-strength training amongst institutionalized seniors.

All of the mealtime factors explored in this study could also have been affected by the level of difficulty of the diet textures offered at meals. Diet texture may represent a scale of difficulty, but this has not yet been proven within the dysphagia literature. A study performed by Kays and colleagues (Kays, Hind, Gangnon, & Robbins, 2010) measured the tongue strength of older, healthy adults (aged 65-82) before and after consumption of a meal consisting of half a
bagel with peanut butter, carrot sticks and milk. The results showed that the activity of eating a meal can be tiring enough to cause reduced post-meal measures of tongue strength compared to pre-meal measures. In the current study, we were unable to control for the textures of foods served at meals. This is a factor that should be carefully monitored in future studies. Related considerations, which would be interesting to explore in future studies, include dental health and the presence of functional teeth or dentures, which are known to impact the time required for food intake (Krall, Hayes, & Garcia, 1998; Sheiham et al., 2001). Similarly, medications were not considered in this study, but may affect both appetite and lethargy at meals, with consequences for measures of mealtime function and duration.

In summary, there are several limitations to acknowledge regarding this study. The first is the very small, heterogeneous sample of LTC residents enrolled; results might differ with a larger sample size comprised of more similar residents. The residents in our study had a wide variety of diagnoses, as seen in Table 2. While the heterogeneity of the sample is likely to be representative of the LTC population, overall impairment due to each individual’s combination of diagnoses may have affected results of both the tongue strengthening therapy and mealtime function. It is possible that some residents performed better or worse as a consequence of their diagnoses. The enrollment of residents based on low tongue strength alone is another limitation. The absence of a confirmed swallowing problem created a ceiling effect that prevented the likelihood of seeing change in the dependent variables of mealtime function.

The inclusion of no-treatment control group would also be beneficial in future investigations to explore whether individuals who do not receive the intervention decline in their functional mealtime outcomes compared to residents who receive treatment. Another limitation of the current study was the limited number of post-treatment mealtime observations, which may not have been adequate to obtain a representative sample of each resident’s mealtime performance compared to the longer pre-treatment surveillance phase. Access to an instrumental assessment like a videofluoroscopy swallowing study would have allowed us to more specifically target and enroll residents with confirmed dysphagia, who might have been more likely to demonstrate measurable benefits from tongue pressure training.

In conclusion, this proof-of-principle study has shown that tongue-pressure resistance training can be used successfully in the LTC setting, and that individuals with living in LTC are
able to participate and achieve improvements in both anterior and posterior tongue strength, despite the presence of cognitive impairments. There was a clear difference between baseline and outcome tongue pressures for six out of seven LTC residents in this study, four of whom had a confirmed diagnosis of dementia. However, despite these improvements in tongue pressures, we were unable to identify associated improvements in measures of mealtime function, such as mealtime duration, amount of food consumed and number of mealtime difficulties. Future investigations of the effectiveness of tongue-pressure resistance training in this population should include comprehensive swallowing assessment and a no-treatment control group to confirm the degree to which change in measures of mealtime function can be expected as an outcome of tongue strength training.
References


Chapter 6
Summary of Contributions and Future Directions

Dissertation Summary
At the outset of this dissertation my ultimate goal was to better understand how dysphagia and nutrition were related. The relationship between dysphagia and malnutrition appears logical; if one is unable to swallow efficiently and/or effectively how could they possibly receive the nutrients required to thrive? And, if they are not receiving the nutrients their bodies require then they will eventually become malnourished. Many researchers cite malnutrition as a consequence of dysphagia, but citations from the literature are rarely provided to support this claim. However, if a link can be shown, clinicians and researchers would have a better understanding of the influence of dysphagia on malnutrition and could create interventions with functional mealtime outcomes, which would in turn support both efficient and safe swallowing, as well as proper nutrition. I chose a population, residents of long-term care (LTC), in whom malnutrition is a prominent concern (Nelson, Coulston, Sucher, & Tseng, 1993), who would also be prone to dysphagia given the high rates of dementia and neurodegenerative disease (Seitz, Purandare, & Conn, 2010). My original assumption was that this would be an easy population in which to demonstrate the hypothesized relationship. This presumably straightforward and reasonable proposition proved to be much more complex.

This dissertation was carried out in three phases. First, it was important to investigate the previous literature, in order to determine what has been documented regarding the co-occurrence of malnutrition and dysphagia in elderly residents of LTC. I conducted a systematic review (Chapter 2) to capture how both malnutrition and dysphagia were described and measured in the LTC setting. It was surprising to find such a small number of peer-reviewed research articles reporting both conditions, and to identify limitations of the available literature with respect to wide variations in the definitions and measurement tools used. It was evident that standard definitions and measures were required to better understand each condition’s prevalence and the co-occurrence of the two conditions. This motivated the second phase of this dissertation, namely the collection of swallowing and nutrition data using clear definitions and measures in a sample of elderly LTC residents. The first study in this phase (Chapter 3) was a feasibility study; we wanted to ensure that we could collect tongue pressure data, perform a
screening for dysphagia, and gather information regarding mealtimes, such as mealtime
duration, amount of food consumed and number of mealtime difficulties. Once the pilot study
proved to be successful and trends were apparent even in our small sample of 12 residents from
a single LTC home, we continued on to a much more comprehensive study with a sample
comprising residents from 32 different LTC homes across the country (Chapter 4). Through this
larger study, we found evidence that low swallowing pressures are associated with increased
risk of dysphagia, and that risk of dysphagia, in turn, is associated with a greater likelihood of
malnutrition. We also discovered that residents with low swallowing pressures took longer to eat
compared to those who had relatively higher pressures. Moreover, those who had both low
pressures and were found to have signs of dysphagia ate fewer calories per minute, compared to
those with higher pressures and no signs of dysphagia. Thus, concrete evidence of associations
between tongue weakness, dysphagia and malnutrition risk was established. These findings
prompted the final phase of this dissertation (Chapter 5), in which a proof-of-principle tongue
strengthening intervention was trialled in one LTC home with seven residents. The goal was to
determine whether tongue strengthening was possible in residents with cognitive impairments,
and if a stronger tongue would positively influence functional mealtime outcomes. The findings
confirmed the feasibility of delivering a tongue strength training intervention in this population,
and showed effectiveness in terms of tongue strength outcomes. However, perhaps due to the
fact that the participants who were enrolled had not yet developed clinical signs of dysphagia,
no impact on mealtime outcomes was seen.

Summary of Unique Contributions
Taken together, the results of this dissertation research offer several novel insights for the
dysphagia community. Each contribution and its potential impact is discussed below.

Co-occurrence of Malnutrition and Dysphagia
The results of this dissertation have made it particularly clear that when clearly defined and
carefully measured, malnutrition and dysphagia co-occur in at least 29% of elderly residents
living in LTC. The likelihood of this co-occurrence was alluded to in the systematic review
described in Chapter 2, but given the range of measurements used and unclear definitions both
of dysphagia and malnutrition, firm conclusions could not be drawn. The pilot study in Chapter
3 also suggested that the two conditions were linked, but the small sample size and indirect measurements of nutrition (mealtime duration and amount of food consumed) prevented us from drawing any finite conclusions. Finally, in Chapter 4, with a sample of 638 LTC residents, we were able to show not only that the two conditions co-occur, but also that the odds of being malnourished were almost double if a LTC resident showed signs of dysphagia, and that this relationship was significant ($\chi^2(1) = 8.520$, $p<0.05$; odds ratio = 1.62, 95% confidence interval: 1.17-2.24). While it is well understood that the causes of malnutrition are multifactorial (Evans, 2005), these data demonstrate a specific association between dysphagia and malnutrition. This finding has the potential to inform the way that clinicians and researchers assess the impact of dysphagia and choose outcome measures. For example, the evidence from our studies shows that mealtime duration was significantly longer in those classified with suspected dysphagia, indicating that those who take a shorter amount of time to eat are less likely to have dysphagia, and consequently are less likely to be malnourished. Moving forward, mealtime duration, using the reference values from our study, may be a measure that can be easily integrated into assessment procedures and outcome measures.

**Maximum Isometric Pressures are Maintained but Swallow Pressures are Reduced**

Another contribution of this dissertation is the novel demonstration that the anterior maximum isometric tongue pressures of elderly living in LTC do not differ substantially from those seen in elderly adults living in the community, as reported by Vanderwegen and colleagues (Vanderwegen, Guns, Van Nuffelen, Elen, & De Bodt, 2013). The LTC residents in our study had maximum isometric pressures averaging 32.63 kPa (95% CI: 28.71-36.55), as reported in Chapter 4. This finding was somewhat surprising given the vulnerable and frail nature of the LTC residents. By contrast, we found that swallowing pressures were reduced compared to those reported in previous studies in older, healthy adults. The elderly residents in our study had a mean swallow pressure of 25.61 kPa (95% CI: 22.66-28.56), compared to 29.6 kPa as reported by Youmans and Stierwalt (Youmans & Stierwalt, 2006). This is the first study to suggest that the overall strength of the tongue in the very elderly is maintained, while the amount of force used to actually swallow is diminished. Prior studies have concluded that overall tongue pressure reduces after the age of 70 (Vanderwegen et al., 2013). Chapter 4 also pointed out that the difference between swallowing pressures and maximum pressure generation capacity (also
called “functional reserve”) is extremely limited in the elderly adults living in LTC. Previous reports have suggested that older adults generally use 45.9% of their maximum isometric pressure range to swallow (Robbins, Levine, Wood, Roecker, & Luschei, 1995). In our study, participants from LTC were using, on average, 88.2% of their maximum isometric pressure range. Interestingly, maximum swallow pressures measured as a percentage of maximum isometric pressures did not have an association with suspected dysphagia; in other words, those who used a larger percentage of their maximum isometric pressure in order to swallow were not more likely to have signs of dysphagia. This finding appears to contradict previous hypotheses that functional reserve may be a meaningful measurement (Nicosia et al., 2000). These contributions will impact future research by providing normative data tongue pressure for elderly living in LTC. Further, these findings provide evidence to suggest that the focus of tongue pressure training should perhaps be on swallowing pressures, rather than maximum isometric pressures.

Reduced Swallowing Pressures are Associated with Dysphagia
Within the field of dysphagia, screening has been recommended for anyone in a recognized risk group. Research has shown that early screening for dysphagia in acute stroke patients reduces the occurrence of aspiration pneumonia, mortality and the need for tube feeding (Martino et al., 2005). Another study performed by Hinchey and colleagues, suggested that hospitals employing formal screening approaches had a lower incidence of subsequent pneumonia compared to those informal approaches (Hinchey et al., 2005). More recently, Bray and colleagues found that even delays in screening for and assessing dysphagia are associated with higher rates of pneumonia (Bray et al., 2016). While all three of these studies were evaluating the implementation of screening tools in post-stroke patients, they all highlight the importance of swallowing screening. The findings in my dissertation suggest that the evaluation of swallowing pressures in the LTC setting may have utility as an approach to finding individuals at risk for dysphagia. We found swallowing pressures to be notably lower in residents classified as having suspected dysphagia compared to those without. More specifically, residents who had swallowing pressures below 25.61 kPa were 3.7 times more likely to be classified as having dysphagia than those with swallowing pressures above 25.61 kPa. Importantly, these reference values can be used when screening for dysphagia in elderly residents of LTC.
Tongue Pressure Training is Feasible in LTC and with People with Cognitive Impairments

While the feasibility of tongue pressure training has been demonstrated in post-stroke (Steele et al., 2016), brain injured (Steele et al., 2013), and head and neck cancer patients (Lazarus et al., 2000), the research in this dissertation is the first to trial a tongue pressure training protocol in the LTC population. To our knowledge, tongue pressure training has also never been trialled in a sample with cognitive impairments, such as dementia. This dissertation research was able to demonstrate that elderly adults living with mild to moderate cognitive impairments in LTC are able to participate in 16 sessions of a tongue strengthening intervention. More importantly, both anterior and posterior maximum isometric pressures increased significantly as a function of the intervention. It is important to note that the chosen intervention focused on tongue pressure strengthening and accuracy targets, rather than swallowing. Any treatment protocols that integrate swallowing may show different results. With this information, researchers and clinicians can confidently implement similar interventions in order to improve tongue strength, if warranted.

Limitations

There are several limitations to acknowledge in this dissertation. First, the dysphagia-related findings in all experimental chapters deal exclusively with dysphagia screening rather than more objective methods of assessment. The purpose of a screening is to determine the need for an assessment. It elicits an answer regarding the risk of a condition; it does not determine if a participant has a condition. A formal swallowing assessment would have confirmed the presence or absence of dysphagia. As such, our results are limited to discussing the presence of signs and risk of dysphagia with no certainty regarding an actual diagnosis. The current gold-standard for evaluating dysphagia is a videofluoroscopic swallowing study (VF; i.e., a dynamic x-ray). Unfortunately, it was not feasible to take residents out of their LTC homes in order to perform these studies, and the procedure would have been extremely costly. However, information from a VF would have provided us with much more detail regarding the pathophysiology of each resident’s swallow, and would have better informed the intervention. Fiberoptic endoscopic evaluation of swallowing could not be used as an alternative due to regulatory barriers. My decision to use swallow screening measures rather than more detailed assessment was based solely on feasibility. Similarly, residents who participated in the
intervention described in Chapter 5 were enrolled on the basis of reduced tongue strength rather than dysphagia, which is a further limitation of this dissertation. Had residents been enrolled based on the confirmed presence of dysphagia, as evaluated through a VF, the therapy could have been targeted to the swallowing pathophysiology of each resident and, as a result, we might have seen improved mealtime outcomes. We would have also been able to evaluate dysphagia-related outcomes in a more precise manner.

The fact that dysphagia risk was described as a composite variable is another limitation of this research. The Screening Tool for Acute Neuro Dysphagia (STAND) was only performed on residents who did not have any thin liquid restrictions. This limitation was specifically requested by the ethics review boards for several of the LTC facilities, due to concerns that the 90ml water drinking task might pose a risk of aspiration in individuals who already required thickened liquids. Consequently, a small subset of the overall sample could not participate in the swallow screening process. We assumed that those who were restricted only to thickened liquids were previously identified as having dysphagia and categorized them as such. There were also residents who may have successfully completed the STAND, meaning that they did not show any signs of swallowing difficulty with the puree trials and water swallow test, but who showed signs of coughing and/or choking at mealtimes. These residents were also included as having suspected dysphagia despite the results of the STAND, and despite the STAND’s reported high sensitivity and fair specificity (92% sensitivity and 60% specificity for detecting dysphagia in stroke patients (Shephard, 2007)). Moreover, any residents who were not on thickened liquids and did not complete the STAND due to poor cognitive status, yet coughed and/or choked at mealtimes were also included in our composite variable of dysphagia risk. As one can see, many assumptions were made in order to form this composite variable but these were necessary in order to classify dysphagia risk in as many residents as possible. The estimated prevalence of dysphagia risk from this study might have been different, if it had been possible for all residents to have been screened in the same way.

Another limitation of this dissertation is the fact that the tongue strength measures taken in this study may not be representative of the tongue strength of the wider population of all LTC residents. Measurements were restricted to those who were alert, could sit upright and could follow simple directions. The cognitive status of LTC residents varies considerably, meaning
that many residents were unable to participate in the tongue strength assessment procedures. The data presented within this dissertation reflect the tongue strength of residents who were more cognitively aware. It is possible that reference values would change if all LTC residents were able to participate.

**Future Directions**

In future research, it would be desirable to repeat the methods in Chapter 4 but also use a VF to confirm the presence of dysphagia in residents showing signs of swallowing impairment based on the composite variable of dysphagia risk. Performing a more comprehensive evaluation after screening for dysphagia would allow for confirmation of the condition, and this information could then be used to more precisely calculate the co-occurrence of malnutrition and dysphagia. Although this dissertation takes a first step in describing the prevalence and clinical signs of dysphagia in LTC residents, we have yet to quantify the impairments and pathophysiological changes in swallowing that exist in this population. If videofluoroscopy could be obtained, the physiological parameters of swallowing that are impaired in residents of LTC can be investigated using more objective measurements (e.g., (Molfenter & Steele, 2014; Nagy, Molfenter, Péladeau-Pigeon, Stokely, & Steele, 2015; Pearson, Molfenter, Smith, & Steele, 2013; Stokely, Peladeau-Pigeon, Leigh, Molfenter, & Steele, 2015)). Further, the functional consequences of any observed physiological impairments on swallowing safety (i.e., material entering the airway) and swallowing efficiency (i.e., material remaining in the pharynx after the swallow) could be explored. It would be most important to evaluate key physiological parameters of swallowing, including timing and degree of airway closure, velocity and maximal displacement of hyoid movement, and constriction of the pharyngeal lumen during swallowing. These are parameters that have been reported in previous research as risk factors for swallowing safety and efficiency in older adults who were experiencing, or at risk for, dysphagia (Molfenter & Steele, 2014; Steele, 2015). This information would provide support for investigating novel dysphagia management strategies and potential targets for rehabilitation in LTC.

It would also be ideal if future studies could further explore tongue strengthening interventions in LTC, similar to that studied in Chapter 5. Future studies should focus on increasing swallow pressures, rather than maximum isometric pressures, and include a no-
treatment control group to determine whether the intervention helps with maintenance or improvement of mealtime outcomes post-intervention. A later follow-up would also provide valuable knowledge for the dysphagia community, in term of evaluating any de-training effects and the long-term benefits of the intervention (i.e., do residents in the treatment group remain on non-modified diets for a longer period of time compared to those in the no-treatment control group?). Such a study involving mealtime observations should also incorporate the measurement of maximum tongue strength and endurance (duration that 50% of maximum tongue strength can be maintained) before and after each meal in order to evaluate fatigue. This would allow us to better understand fatigue of the tongue in this population, and would add to the findings previously reported by Kays and colleagues (Kays, Hind, Gangnon, & Robbins, 2010), who measured strength and endurance in healthy older adults and found reduced tongue strength and endurance after dining. This information can be used to then clarify the effects of observed decline in tongue endurance on physiological swallowing measures, including airway invasion, through the use of pre- and post-meal instrumental swallowing assessments.

Finally, as the relationship between swallowing and nutrition is quite complex, it would be interesting to determine the effects of nutritional supplements on tongue strength, without the use of a tongue strengthening intervention, in a nutritionally vulnerable group. A multidisciplinary study of this nature would convey the importance, if any, of proper nutrition on tongue strength maintenance, and would inform both researchers and clinicians of holistic approaches to swallowing rehabilitation.

Conclusion
This dissertation was broadly motivated by a desire to better understand the relationship between nutrition and dysphagia. Specifically, I set out to describe the co-occurrence of malnutrition and dysphagia in LTC, identify the impact of dysphagia on malnutrition, understand how reduced tongue strength relates to dysphagia and mealtime outcomes, and apply these findings in a tongue strengthening intervention in LTC. Taken together, this work makes several novel contributions to the dysphagia community. I have established that dysphagia and malnutrition do co-exist in LTC, and that the odds of malnutrition are increased in the presence of signs of dysphagia. This dissertation has demonstrated that reduced swallowing pressures and
longer mealtimes are closely linked to signs of dysphagia, and that suspected dysphagia increases almost four-fold in the context of reduced swallowing pressures. I have shown that tongue strength can be improved in people with cognitive impairments living in LTC, but it remains unclear whether mealtime outcomes respond to these changes. Finally, this dissertation contributes the first set of reference values for tongue strength for residents of LTC. In conclusion, several limitations have been acknowledged and this work has raised further questions regarding how to best screen for and assess dysphagia in LTC, and the most appropriate dysphagia-related interventions in this setting. This work has allowed me to pair my clinical training with robust methods of scientific discovery in the pursuit of better understanding dysphagia and minimizing its impact; the questions raised will fuel my passion for this subject matter for many more years to come.
References


Appendix A: Ethics Documents

Ethics protocol

Title: Making the Most of Mealtimes (M3): Determinants of food intake in long term care -- pilot study. Subproject: Tongue strength as a predictor of food intake.

Principal investigator: Catriona M. Steele, PhD (Toronto Rehab Institute)

Co-investigator: Ashwini Namasivayam, Doctoral Student (University of Toronto)
1. Background, Purpose, Objectives

**Background**

*Malnutrition in Long Term Care*

The fastest growing segment of the population in Canada is the elderly (Statistics Canada, 2011). They have the highest rate of illnesses, disease, and disability, all of which may be implicated by malnutrition. This is often under-recognized by health care professionals (Cope, 1996; Dudek, 2000; Thomas, Morley, Ashman, & Evans, 2000; Reuben, Effros, Hirsch, Zhu, & Greendale, 1999; Wilson, Vaswani, Liu, Morley, & Miller, 1998). Important factors such as weight loss, undereating, obesity, diabetes and sarcopenia can end up driving these individuals into nursing homes (Bourdel-Marchasson et al., 2007; Bourdel-Marchasson et al., 2004; Elkins et al., 2006; Zizza et al., 2003). Once these individuals are within the confines of a LTC facility, malnutrition can easily take over.

Malnutrition is often the result of suboptimal food intake (Aghdassi et al., 2007) if not a secondary consequence of acute or chronic disease (Bourdel-Marchasson et al., 2009), subsequently increasing the risk of micronutrient deficiencies (Nes, Sem, Pedersen, & Trygg, 1992; Wahlqvist, Kouris-Blazos, & Savige, 1998; Wendland, Greenwood, Weinberg, & Young, 2003). Without these critical nutrients the elderly residing in LTC homes are prone to functional incapacity, a reduction in immune response, an increased susceptibility to infection and other chronic diseases, not to mention a reduced quality of life, in addition to an increased chance of hospitalization, morbidity and mortality (Cope, 1996; Dudek, 2000; Keller, 1993). There are also instances where the elderly are said to have normal nutritional statuses based on indicators frequently used in said facilities, yet still do not meet the recommended levels of intake for protein and micronutrients (Aghdassi et al., 2007). Some even have a normal BMI (Aghdassi et al., 2007). Unfortunately, malnutrition is often left untreated (Sullivan, 1995). One study performed demonstrated how nurses working in LTC underestimated the incidences of malnutrition (McWhirter & Pennington, 1994). This may contribute to the clear relationship between malnutrition and the rate of in-hospital complications and re-admissions (Landi et al., 2000; Omran & Morley, 2000; Lo´pez-Contreras et al., 2010).

While nutritional parameters can be used to predict in-hospital mortality, the confounding effects of non-nutritional risk factors has proven to be difficult to assess (Detsky et al., 1984; Constans et al., 1992). And, few studies have investigated these issues within the elderly living in LTC (Keller, 1995). Most of what we know about solutions for malnutrition with the older segments of our population have been developed and tested in acute care and primary care settings (e.g., Dourmit, Gattellari, Grimshaw, & O’Brien, 2007; Farmer et al., 2008; Forsetlund et al., 2009; Grimshaw et al., 2004; Jamtvedt et al., 2006). Unfortunately, the findings from these studies cannot be generalized to those residing in LTC.
settings, as substantial differences exist between care of the elderly in the hospital and those in LTC. Reports of malnourishment currently in LTC facilities tend to range anywhere from 5% to 70%. Bauer and colleagues (2008) have attributed this broad range in prevalence to the extent of individual dependence of those who live in care settings. As such, a focus needs to be given to the nutritional status of the residents in LTC (Boström, Van Soest, Kolewaski, Milke, & Estabrooks, 2011) by staff, physicians, managers, and researchers alike. A lack of evidence-based practice in this area could be costing the Canadian healthcare system unnecessary money.

Consequences of Malnutrition in Long Term Care

The risk factors for malnutrition amongst LTC residents have been classified into three categories: social factors (e.g. poverty, social isolation), psychological factors (e.g. depression and dementia), and medical factors (e.g. poor dentition, cardiac failure, infection, multiple medications, dysphagia) (Chapman, 2006). Associations have also been drawn between malnutrition and dementia and swallowing difficulties, amongst other factors (Suominen, 2005; Odlund, Koochek, Liungqvist, & Cederholm, 2005). It has been shown that in geriatric institutions chewing problems, a type of oral dysphagia, is a risk factor for a low BMI or weight loss (Blaum, Fries, & Fiatarone, 1995). Based on these pieces of evidence, it quickly becomes apparent that swallowing disorders may play a key role in the malnourishment of those in LTC. Currently, most interventions that have been reported to either improve or maintain nutritional status fall into one of three groups: changing environmental factors, adding resources for supporting residents during mealtimes, and modifying the food. However, to determine which of these three categories, if any, might be best suited to residents in LTC, it is critical that an adequate understanding of the cause of the problem is established.

The Tongue and Dysphagia

It is generally accepted that normal aging is accompanied by decreases in strength and changes in skeletal muscle, which comprises the bulk of the tongue. Loss of skeletal muscle mass around the body generally occurs after the age of 60, due to muscle atrophy and motor neuron loss (Larrson, 1978). The normal process of aging is also associated with muscle-wasting conditions, such as sarcopenia and cachexia, both of which can have an impact on nutritional status. Sarcopenia can be described as an age-related shift in body composition, specifically the loss of muscle mass. Cachexia, which is a complex metabolic syndrome associated with an underlying illness that is characterized by loss of muscle with or without the loss of fat, has also been identified in residents of LTC (Thomas, 2009; Chapman, 2007; Landi, Layiano, & Cruz-Jentoft, 2010). While these changes seen in major muscle groups may also occur in the tongue, there is little evidence that this causes any clinical deficits.
Swallowing involves a series of three phases: oral, pharyngeal, and esophageal. Each of these phases requires several muscles and nerves to be in tact in order to facilitate a safe and efficient swallow. Dysphagia, or a swallowing disorder, occurs when any of the muscles or nerves involved in swallowing are damaged or become weak, and material from the swallow is entering the area or there is sufficient residue left behind. Medical recovery is negatively impacted by dysphagia, which often causes longer hospitalization and an increased need for LTC (Odderson, Keaton, & McKenna, 1995). A common sequela of dysphagia, aspiration pneumonia, is associated with a significant risk of for morbidity and mortality (Shariatzadeh & Marrie, 2006). Appropriate tongue strength is crucial to help avoid these problems, as it is essential for the oral and pharyngeal phases of swallowing. The tongue contributes to the formation, placement, and manipulation of the bolus within the oral cavity, and propulsion into the pharynx (see Figure 1) (Youmans & Stierwalt, 2006). If any of the eight muscles of the tongue become weak, its functions can easily become hindered. As such, it is important that the implications of a weakened tongue are understood, especially in regards to those who are in LTC and are at risk for malnourishment.

The tongue is a muscular hydrostat (Kier & Smith, 1985), meaning its mechanical effect is dependent upon the integrated activity of the other muscles within the organ (Kairaitis, 2010). Additionally, it is composed of both Type I and Type II muscles fibres. While Type II fibres, those that are fast-twitch and fatiguable, are predominant, the tongue tip is made up of mostly Type I fibres, those that are slow-twitch and fatigue-resistant (Kent, 2004). The anterior portion of the tongue performs more endurance activities, such as talking, so fatigue-resistance is a key feature. If this portion of the tongue were to lose muscle as one ages, it is possible that fatigue may set in faster than usual, inhibiting some portion of the swallowing functions. Identifying more effective methods of diagnosis and treatment has been
designated as a top priority in rehabilitation research (Robbins, Langmore, Hind, & Erlichman, 2001), in order to improve the health and quality of life and decrease fatalities in those with dysphagia.

**Fatigue and Strength of the Tongue**

Muscle fatigue can be described as an acute reduction in the ability to exert muscle force, independent of whether the force can be sustained (Gandevia, 2001). Fatigue is a commonly reported condition in older adults (Poluri, Mores, Cook, Findley, & Cristian, 2005), and has pervasive effects on many activities of daily living, including dining. Older adults who are at risk for or have been diagnosed with dysphagia often report that it takes them longer to eat than others, and swallowing is more difficult at the end of the day (Roy, Stemple, Merrill, & Thomas, 2007). Given the tongue’s role in swallowing, it is conceivable that an age-related reduction in tongue strength increases the physiological demands of mealtimes, consequently reducing one’s overall food intake and contributing to malnutrition over time. In a study of 10 young adults who ate a 1,000 calorie meal, a total of 440 solid boluses were observed, suggesting an average of 44 solid bolus swallows per individual (Dua, Ren Barden, Xie, & Shaker, 1997). These data indicate that the consumption of an entire meal, which demands multiple swallows of various textures, volumes and consistencies, definitely is a strength task that has the potential to induce fatigue.

Many studies have been published on tongue strength on both healthy and disordered populations, but mostly concentrate on speech production rather than swallowing (e.g., Goozee, Murdoch, & Theodoros, 2001; Robin, Goel, Somodi, & Luschei, 1992; Chang, Chen, Ko, & Lin, 2008). Research in the area of tongue strength as it relates to swallowing tasks are only recently emerging. Standard evaluation techniques for potentially dysphagic patients are based on an oral mechanism exam, which subjectively evaluates the strength and function of the muscles and nerves of the oral cavity, as well as swallows performed at the bedside or during an instrumental examination. With these methods, any judgments made about tongue strength may not be accurate. Moreover, judgments about the effectiveness of a treatment strategy, ideally designed to enhance swallowing safety and efficiency, with practical extensions to mealtimes, are based on the immediate outcomes of only several swallows and fail to capture the potential for fatigue over the course of an entire meal. To simulate the demands of a meal experience when decreased strength is expected, Logemann (1998) suggests observing patients instrumentally prior to and after eating a meal. When Kay and colleagues (2010) used this technique to determine if tongue strength in healthy old and young adults, they found that all subject demonstrated reduced tongue strength postmeal. Since it is clear that meal consumption is sufficient to fatigue older, healthy people, it is logical to determine the impact of meal consumption on the elderly living in LTC who have health issues, as they are the segment of the population who are suffering the most from malnutrition. If we can determine if tongue strength is impacting meal consumption, and is contributing to malnutrition, then we can develop interventions to mitigate this problem. In turn, this research will help to improve the quality of life of those in LTC, possibly prolong these residents’ lives, while saving the healthcare system thousands of dollars because of reduced hospital admissions.
Purpose

The purpose of this study is to describe whether tongue strength is associated with food intake in elderly residents in a long term care facility. This will help us to better understand how tongue strength impacts the length of time taken to eat a meal and the amount of food consumed. We hypothesize that those with reduced tongue strength will take longer to finish eating and will eat less than those residents whose tongue strength falls within the norms.

2. Research Methodology and Data Collection

Participants

We will enroll a prospective sample of 25 qualifying long term care residents. All residents, regardless of cognitive ability, will be eligible to participate if they are: residing on the units selected; over the age of 65 years; require at least 2 hours per day of nursing care due to dependence in activities of daily living (i.e. bathing); can follow simple, one-step directions; have resided in the home for at least 3 months; and, either they or their substitute decision maker provide consent to participate. Unit staff will identify those meeting our inclusion criteria. Residents will be excluded if they have been in the care home for less than three months; are currently medically unstable (i.e., < 1 month acute care hospitalization); are on a short-term admission (e.g. respite); require tube feeding; residents who are not eating because they are end of life; or have advanced directives excluding them from research. Eligible residents from the units selected for data collection will be randomly sampled to attain the home’s quota of 20-25 participants. Age, gender, activities of daily living, and cognition (Cognitive Performance Scale from the Minimum Data Set) will be noted for all eligible residents, to determine representativeness of participants.

Home staff will initially approach those residents randomly selected for participation. If they indicate interest, their name/room number will be provided to research staff. In the event that a resident does not have the cognitive capacity to complete their own consent (based on their Minimum Data Set Data, Cognitive Performance Scale), home staff will contact the family substitute decision maker via telephone, using a predefined script, to determine their interest in being approached by research staff to hear more about the research. Once verbal consent has been provided to have a researcher speak to the resident and/or family, the researcher will make contact and review the procedures with the potential participant/family member. A detailed information letter and written consent form will be provided and completed prior to data collection.

Sample Size

This is a pilot study so only 25 participants will be enrolled.
**Data Collection**

Data will be collected at unit and resident levels to describe and identify determinants of inadequate food intake. Time for data collection in each home is driven primarily by the collection of 3 days of food intake data and meal observations for each participant. It is estimated that 1 month (20 working days) per home will be required to collect all data, to begin in January 2014.

For the unit-level data collection, three meals on each participating unit will be randomly selected to identify the number and type of staff, family, and volunteers in the dining room. More specifically, the number of eating assistants will be noted. Measures will be averaged across observations.

For the resident-level data collection, three nonconsecutive days of estimated food intake will be collected from all participants. A trained research assistant (RA) will weigh each full food tray, including utensils and napkin, before and after the participant has eaten using a scale. Up to four residents per meal eating in the same dining area will be observed by two trained RAs; residents who eat in their room will be accommodated by the inclusion of a third observer. Residents who are away from the home for a meal will not be observed on that day. Reference main plates/ Portions (pureed, minced, regular texture) will be weighed at the beginning of meal service; observers will note by estimation if offered food is different in portion size from the reference (i.e., a half portion). RAs will also be using a timer to determine the length of time for each of the participants to complete eating their meals.

Determination of malnutrition is needed to characterize the population and be considered as a potential covariate in analyses. The *Mini Nutritional Assessment – Short Form* ® (MNA-SF) (Appendix I) will be used for this portion of the data collection. This short-form screening tool includes body mass index, weight loss, calf circumference, and functional parameters accessed from the health record. Seated or supine knee height will be used to estimate standing height using valid equations (Hickson & Frost, 2003). Body weight will be measured with standardized procedures (Niezgoda, Trainor, Chambers, Keller, & Caissie, 2011) and body weight history taken from the health record for the prior six months. Calf circumference will be collected using standardized procedures and gender-specific cut-points (Isenring, Banks, Ferguson, & Bauer, 2012). Using a MNA-SF score of ≥11 as normal, this tool has a sensitivity of 97.9% and a specificity of 100%, as well as a diagnostic accuracy of 98.7% for predicting undernutrition (Rubenstein, Harker, Salva, Guigoz, & Vellas, 2000).

Resident health records will be reviewed for factors (e.g., diagnoses, medication use, ethnicity, gender) required to describe the sample and selected variables will be used in regression analyses. Number of prescribed medications and use of sedatives, psychotropics or antibiotics will be included in analyses.
Current infection which may impair food intake will be determined using consensus guideline criteria specific to LTC populations (e.g., signs and symptoms) (Stone et al., 2012).

Figure 2. IOPI system.  
Figure 3. IOPI biofeedback.

Measures of tongue strength will be taken using the Iowa Oral Performance Instrument (IOPI), before and after each of the 3 meals being observed. The IOPI is a handheld pressure bulb system that consists of a small air-filled bulb (see Figure 2) that senses pressure when squeezed between the tongue and the hard palate. In consultation with the manufacturer, we have developed a LabView software program to register a digital pressure waveform from the analog signal generated by the IOPI at 250 Hz (see Figure 3); this enables us to provide a biofeedback screen view of the tongue pressure measurement to the participant during data collection, and to extract detailed measures of tongue pressure amplitude and timing. Maximum isometric tongue pressure will be recorded across a series of three bulb squeezes, with the bulb held in an anterior position, just behind the teeth (see Figure 4). A value of 55kPa of greater will be considered normal for the population of interest in this study, whereas anything lower
than 55kPa will be considered weak (Stierwalt & Youmans, 2007). Additionally, saliva swallows will be recorded across a series of 3 cued tasks, with the bulb held the same anterior position. Tongue pressure tasks will be cued with a 10 second rest between each task repetition. In total, 2 minutes will be required to collect the tongue pressure measures. A clean, individually wrapped, single-use tongue pressure bulb will be used for each participant, and disposed of immediately after use.

Figure 4. IOPI anterior bulb placement.
3. Data Processing and Analysis

**Data Processing**

After completion of the nutrition and dysphagia screenings, as well as the tongue pressure tasks and the mealtime observations, data will be labeled with a non-identifying study code number and saved to a secure, password-protected, encrypted data base on the research server.

**Statistical Analysis**

The effect of tongue strength on meal consumption for residents in long term care will be determined using a one-way analysis of variance (ANOVA) with a factor of tongue strength (< 55kPa or > 55kPa, where a value of 55kPa or above is being considered normal), and a repeated factor of meals (1-3).

4. Recruitment and Informed Consent

Home staff will initially approach those residents randomly selected for participation. If they indicate interest, their name/room number will be provided to research staff. In the event that a resident does not have the cognitive capacity to complete their own consent (based on their Minimum Data Set Data, Cognitive Performance Scale), home staff will contact the family substitute decision maker via telephone, using a predefined script, to determine their interest in being approached by research staff to hear more about the research.

Once verbal consent has been provided to have a researcher speak to the resident and/or family, the researcher will make contact and review the procedures with the potential participant/family member. A detailed information letter and written consent form will be provided and completed prior to data collection. Only after confirming the participant has understood all of the information that is provided and after verifying they have no more questions, can they sign the consent form. A copy of the consent form will be provided to them. When the ability to comprehend the study is in question we will also request consent from the patient’s substitute decision maker prior to enrolling a patient in the study.

5. Risks and benefits

**Risks**

Minimal risks anticipated. All physiological measurements being conducted with residents are part of routine quality nutrition care. For example the measurement of height, weight and arm circumference, no anticipated risks are expected for these measures. A standardized swallowing challenge with small sips of water and applesauce will be used for all residents, excepting those currently consuming thickened fluids. The only potential risk with this assessment is potential aspiration of small amounts of

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food/fluid, which exists on their current diets. The only risks anticipated with mealtime observations are the feeling that residents are being 'selected out' at mealtimes. The only other potential risk is that of research burden for participants due to the number of measures/assessments.

While conducting the tongue pressure tasks there are a few risks to participants. These risks include choking and allergic reaction to the materials being used, but these are no greater than the risks already present at mealtime for all participants. The speech-language pathologist who will be carrying out the data collection has current cardiopulmonary resuscitation certification, and emergency services are available onsite in the unlikely event of a patient arrest. Any such events will be documented according to facility incident reporting requirements. It should be noted that we have conducted swallowing experiments using similar procedures in the Swallowing Rehabilitation Research Laboratory (SRRL) at Toronto Rehab for the past 6 years without any occurrence of serious adverse events.

Benefits
Residents, as part of this pilot, will undergo a detailed nutrition assessment, including screening for swallowing challenges. Findings could result in improved care as these will be communicated back to professional staff at the home as well as the resident or alternate decision maker.

Results of this pilot data will provide much needed information required to ensure that the main study is feasible. If conducted, the main study will provide a comprehensive understanding of the key influencers of food intake. A program of research focused on development of interventions, their implementation and evaluation are planned. Knowledge translation concerning the issues associated with food intake in LTC will result from this main study and will provide the necessary data to support further research and practice change in this area.

6. Privacy and confidentiality

All data will be stored on a computer for offline analysis. Information gathered from participants will be kept confidential and identified using a set of unique alphanumeric codes. All hard copy data will be stored in a secure locked area in the SRRL at the Toronto Rehabilitation Institute. Access to participant information and experimental raw data will be restricted to the investigators named in this proposal. All records will be destroyed after 10 years under the supervision of Dr. Steele.

7. Compensation

There will be no compensation for participation.

8. Conflicts of interest
There are no foreseen conflicts of interest.

9. Scholarly review
Not applicable.

10. Additional ethics reviews
No additional ethics reviews are planned.

11. Contracts
Not applicable.

12. Clinical Trials
Not applicable.

13. Budget
All costs for this study will be covered through the existing staffing resources and student/trainee support funds of the Swallowing Rehabilitation Research Laboratory at the Toronto Rehabilitation Institute – UHN. We anticipate needing a total of 30 staff hours to collect the data. An additional 100 hours are budgeted for data processing and analysis. These will be covered through existing budget dollars assigned to research assistants and trainees in the lab.
REFERENCES


Kairaitis, K. (2010), Is the pharynx a muscular hydrostat?. Medical Hypotheses. 74(3), 590-595


Mini Nutritional Assessment
MNA®
Nestlé Nutrition Institute

Last name:  
First name:  
Sex:  
Age:  
Weight, kg:  
Height, cm:  
Date:  

Complete the screen by filling in the boxes with the appropriate numbers. Total the numbers for the final screening score.

Screening

A  Has food intake declined over the past 3 months due to loss of appetite, digestive problems, chewing or swallowing difficulties?
0 = severe decrease in food intake
1 = moderate decrease in food intake
2 = no decrease in food intake

B  Weight loss during the last 3 months
0 = weight loss greater than 3 kg (6.6 lbs)
1 = does not know
2 = weight loss between 1 and 3 kg (2.2 and 6.6 lbs)
3 = no weight loss

C  Mobility
0 = bed or chair bound
1 = able to get out of bed / chair but does not go out
2 = goes out

D  Has suffered psychological stress or acute disease in the past 3 months?
0 = yes
2 = no

E  Neuro-psychological problems
0 = severe dementia or depression
1 = mild dementia
2 = no psychological problems

F1 Body Mass Index (BMI) (weight in kg) / (height in m²)
0 = BMI less than 19
1 = BMI 19 to less than 21
2 = BMI 21 to less than 23
3 = BMI 23 or greater

IF BMI IS NOT AVAILABLE, REPLACE QUESTION F1 WITH QUESTION F2. DO NOT ANSWER QUESTION F2 IF QUESTION F1 IS ALREADY COMPLETED.

F2 Calf circumference (CC) in cm
0 = CC less than 31
3 = CC 31 or greater

Screening score (max. 14 points)
12-14 points:  
8-11 points:  
0-7 points:  

Normal nutritional status  
At risk of malnutrition  
Malnourished

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  For more information: www.mna-elderly.com
Making the Most of Mealtimes
Determinants of Food Intake in Long Term Care: Pilot Study

PURPOSE OF PROJECT

Professor Heather Keller at the University of Waterloo is leading an initial pilot study to help to determine those measures that are feasible or need to be modified for a larger national study looking at nutritional status (including swallowing/chewing problems, health status, etc.) and food intake in long-term care homes.

SIGNIFICANCE OF THE WORK AND THE NEED FOR THE STUDY

Many factors influence food intake in long-term care, such as the food, the dining atmosphere and the training of staff. At this point, it is unclear which of these factors is the most important and should be the targets for change and improvement. This study is designed to measure a wide range of factors and tease out those that are most important to food intake. Some of the measures to be used in the national study are new and need to be tested to ensure that they can done easily and quickly.

WHO IS ELIGIBLE TO PARTICIPATE IN THE STUDY

Any resident who lives at The Village of Winston Park (LTC) is eligible to participate as long as they:

- are over the age of 65 years;
- have lived at Winston Park for 1 month;
- speak English; and
• volunteer to participate.

Residents are not eligible to participate if they:

• are medically unstable;
• do not live at Winston Park permanently (i.e., respite care, etc.);
• require tube feeding; or
• are in the final stages of life

WHAT WILL YOUR LOVED ONE BE ASKED TO DO?

If you choose to allow your family member to participate, he/she will be asked to:

1. Allow the researchers to use some basic information from their medical record. Specifically, their age, gender, ethnicity, diagnoses, medications, weight history, diet prescription, use of any nutritional supplements and any recent infections or gastrointestinal symptoms (such as nausea) that could influence food intake. Nursing documentation will also be reviewed to determine their overall current health status. The researcher accessing this information will be a health professional and will only access these portions of their chart. He/she will have signed a confidentiality agreement and will be made aware of Winston Park’s policies and procedures around privacy and confidentiality.
2. Allow a health professional to complete an assessment of their body composition by observing his/her muscles and body fat, as well as measuring his/her height (estimated from knee height) and calf circumference. Nursing staff will be asked to report on any recent changes in food intake. A body weight will be taken by nursing staff on a bath day.
3. Allow a dental hygienist to examine his/her mouth and teeth for any potential problems. Your loved one will be asked to answer five questions on chewing ability. If your loved one is not able to
answer questions, a team member will be asked to respond on his/her behalf.

4. Participate in a swallowing screening test with a Registered Dietitian and speech pathologist that involves taking small sips of water from a cup and eating small spoonfuls of applesauce). Tongue strength will also be determined by putting a new, sterile thumb sized balloon on the tip of the tongue and your loved one will be asked to squeeze this to the top of their mouth for 2 seconds; they will be asked to do this three times. In addition, nursing staff will be asked to answer 10 questions on your loved one’s swallowing ability.

5. Have their mealtime experience observed in the dining room and their food intake monitored for three days.

HOW MUCH TIME WILL THIS PROJECT TAKE?

Outside of meal observations that do not require “active” participation, your loved one will spend approximately 1 hour with the research team to collect information. In order to minimize fatigue, testing will be spread out over more than one visit.

WHAT ARE THE POTENTIAL BENEFITS ASSOCIATED WITH PARTICIPATION?

This pilot study will provide the information needed to make sure that the national study is successful. This is the first study of its kind in the world and will provide a strong basis for making changes to support food intake, health and quality of life of long-term care residents.

A short report of specific findings will be provided to you as well as to your loved one if he/she would like a copy. If the research team uncovers any potential health concerns, you will be notified in writing. The Village will also receive a report of any potential health concerns so that they can be followed up appropriately.
ARE THERE ANY RISKS ASSOCIATED WITH PARTICIPATION?

There are no risks associated with this study. All measures are part of standard practice. Data collection will be conducted in private where possible. For residents who require thickened fluids, the swallowing screening test will not be done.

WHAT HAPPENS IF I WANT MY LOVED ONE TO WITHDRAW FROM THE STUDY?

Your loved one’s participation is voluntary and you may decide to stop participation in the study at any time by informing any member of the research team or Kaylen Pfisterer in person, by phone, or by email (her contact information is on the last page of this letter). The care your loved one receives now or in the future through this or any other health care facility will not be affected by your decision to allow him/her to participate or to withdraw from the study. Please note that the research team will ask your loved one if he/she would like to participate prior to conducting any direct measures or observations. Even if you provide consent for the research team to approach your loved one, the final decision about participation rests with your loved one.

WHAT PROCEDURES ARE IN PLACE TO ENSURE CONFIDENTIALITY?

The data collected in this study will be kept confidential. Each participant will be given a participant code that will be used to identify their assessment results. All data will be encrypted and any information that identifies participants will be destroyed after follow up is made with residents and family members on their results. Where a potential health risk is uncovered as a result of the assessment, you (and the Village) will be provided with this information for appropriate follow-up.

Any publications or reports that result from this study will present group data and your loved one’s information will not be identifiable. Coded
Information will be encrypted stored in locked offices and on secure computers at the University of Waterloo and may be retained indefinitely.

**WILL RESIDENTS BE PAID FOR PARTICIPATING IN THE PROJECT?**

Participants will not be paid for their participation in the project.

**HOW WILL I LEARN ABOUT THE RESULTS OF THE PROJECT?**

When the project is finished, you will receive a letter outlining key individual results such as any concerns with nutritional status or swallowing ability. You will also receive an executive summary of overall project findings (such as dining atmosphere) and the research team will present these findings at a residents’ council meeting.

**WHO CAN I CONTACT IF I HAVE QUESTIONS?**

If you have any questions about your participation in this project, or about the recruitment process, please contact Kaylen Pfisterer (Research Associate, Schlegel-UW Research Institute for Aging) at any time (519.571.1873 ext. 109; kpfisterer@uwaterloo.ca).

**HAS THE PROJECT RECEIVED CLEARANCE FROM A RESEARCH ETHICS BOARD?**

This project has been received ethics clearance through a University of Waterloo Research Ethics Committee. If you have any comments or concerns resulting from your loved one’s participation in this study, you may contact Dr. Maureen Nummelin (Director, Office of Research Ethics) at any time (519.888.4567 ext. 36005; maureen.nummelin@uwaterloo.ca).
Making the Most of Mealtimes  
Determinants of Food Intake in Long Term Care: Pilot Study

I have read the information letter describing the project entitled: “Making the Most of Mealtimes Determinants of Food Intake in Long Term Care: Pilot study” being conducted by Professor Heather Keller at the University of Waterloo. I understand the nature of this project and am providing my consent to participate. I have had the opportunity to ask questions about my involvement in this study, and have received satisfactory answers to these questions.

I am aware that:

• I may withdraw from the study without penalty at any time by advising the researchers of this decision. My decision to withdraw from the study will not jeopardize my relationship with the Schlegel Villages, the Schlegel-UW Research Institute for Aging or the University of Waterloo
• by signing this form, I am not waiving any of my legal rights or releasing the investigator(s) or involved institution(s) from their legal and professional responsibilities
• If I have any questions about this project, I can contact Kaylen Pfisterer at the Schlegel-UW Research Institute for Aging (519.571.1873 ext. 109; kpfisterer@uwaterloo.ca) at any time

This project has received ethics clearance through a University of Waterloo Research Ethics Committee. I was informed that if I have any comments or concerns resulting from my participation in this study, I may contact Dr. Maureen Nummelin (Director, Office of Research Ethics) at any time (519.888.4567 ext. 36005; maureen.nummelin@uwaterloo.ca).
I am aware that selected information from my medical chart (medications, diagnoses, body weight, diet prescription, and any recent symptoms that can influence food intake) will be collected by research personnel.

I agree to allow research personnel access to my medical chart. □ YES □ NO

With full knowledge of all foregoing, I agree, of my own free will, to participate in this study.

Resident Name: ____________________________ Name of Witness: ____________________________
(please print) (please print)

Signature: ____________________________ Signature: ____________________________

Date: ____________________________ Date: ____________________________
Making the Most of Mealtimes: Determinants of Food Intake

Pilot study

Script for Determining Assent

The following script will be used when informed consent is provided by an alternate decision maker for the resident. Assent will be needed for physical measures with residents. Objections of people with impaired capacity related to dementia will typically be expressed indirectly by indications of frustration, discomfort, unhappiness or passivity (Slaughter et al., 2007, p. 32). If a resident is unwilling or does not follow instructions, the resident will be re-approached at a later time. If this second time is unsuccessful, the data will not be collected.

For Anthropometric/Nutrition Measures:

Hello {resident name}, my name is Heather. I am here to do a few measures with you to see how you are doing. Can I (each asked individually-a) measure your calf, b) see how tall you are, c) can I take a look at your arm (for Subjective Global Assessment) and your collar bone.

For Swallowing Screen:

Hello {resident name}, my name is Heather. I wanted to check on your swallowing today. Would that be okay? Let’s try a teaspoon of applesauce. Now let’s try a small glass of water.

For Oral Health Screen:

Hello {resident name}, my name is Heather and this is {dental hygienist name}. Is it okay if we look at your mouth today? We are checking to see what your teeth are like.

Reference:

STUDY PROTOCOL

MAKING THE MOST OF MEALTIMES (M3): DETERMINANTS OF FOOD INTAKE IN LONG TERM CARE

SUBPROJECT: TONGUE STRENGTH AS A PREDICTOR OF FOOD INTAKE

PI: Catriona M. Steele, Ph.D.

Swallowing Rehabilitation Research Laboratory

Toronto Rehabilitation Institute – University Health Network
1. Introduction

Section 1.01 Malnutrition in Long Term Care

The fastest growing segment of the population in Canada is the elderly (Statistics Canada, 2011). They have the highest rate of illnesses, disease, and disability, all of which may be implicated by malnutrition. This is often under-recognized by health care professionals (Cope, 1996; Dudek, 2000; Thomas, Morley, Ashman, & Evans, 2000; Reuben, Effros, Hirsch, Zhu, & Greendale, 1999; Wilson, Vaswani, Liu, Morley, & Miller, 1998). Important factors such as weight loss, undereating, obesity, diabetes and sarcopenia can end up driving these individuals into nursing homes (Bourdel-Marchasson et al., 2007; Bourdel-Marchasson et al., 2004; Elkins et al., 2006; Zizza et al., 2003). Once these individuals are within the confines of a LTC facility, malnutrition can easily take over.

Malnutrition is often the result of suboptimal food intake (Aghdassi et al., 2007) if not a secondary consequence of acute or chronic disease (Bourdel-Marchasson et al., 2009), subsequently increasing the risk of micronutrient deficiencies (Nes, Sem, Pedersen, & Trygg, 1992; Wahlqvist, Kouris-Blazos, & Savige, 1998; Wendland, Greenwood, Weinberg, & Young, 2003). Without these critical nutrients the elderly residing in LTC homes are prone to functional incapacity, a reduction in immune response, an increased susceptibility to infection and other chronic diseases, not to mention a reduced quality of life, in addition to an increased chance of hospitalization, morbidity and mortality (Cope, 1996; Dudek, 2000; Keller, 1993). There are also instances where the elderly are said to have normal nutritional statuses based on indicators frequently used in said facilities, yet still do not meet the recommended levels of intake for protein and micronutrients (Aghdassi et al., 2007). Some even have a normal BMI (Aghdassi et al., 2007). Unfortunately, malnutrition is often left untreated (Sullivan, 1995). One study performed demonstrated how nurses working in LTC underestimated the incidences of malnutrition (McWhirter & Pennington, 1994). This may contribute to the clear relationship between malnutrition and the rate of in-hospital complications and re-admissions (Landi et al., 2000; Omran & Morley, 2000; Lo´pez-Contreras et al., 2010).

While nutritional parameters can be used to predict in-hospital mortality, the confounding effects of non-nutritional risk factors has proven to be difficult to assess (Detsky et al., 1984; Constans et al., 1992). And, few studies have investigated these issues within the elderly living in LTC (Keller, 1995). Most of what we know about solutions for malnutrition with the older segments of our population have been developed and tested in acute care and primary care settings (e.g., Dourmit, Gattellari, Grimshaw, & O’Brien, 2007; Farmer et al., 2008; Forsetlund et al., 2009; Grimshaw et al., 2004; Jamtvedt et al., 2006). Unfortunately, the findings from these studies cannot be generalized to those residing in LTC settings, as substantial differences exist between care of the elderly in the hospital and those in LTC. Reports of malnourishment currently in LTC facilities tend to range anywhere from 5% to 70%. Bauer and colleagues (2008) have attributed this broad range in prevalence to the extent of individual dependence of those who live in care settings. As such, a focus needs to be given to the nutritional status of the residents in LTC (Boström, Van Soest, Kolewaski, Milke, & Estabrooks, 2011) by staff,
physicians, managers, and researchers alike. A lack of evidence-based practice in this area could be costing the Canadian healthcare system unnecessary money.

**Section 1.02 Consequences of Malnutrition in Long Term Care**

The risk factors for malnutrition amongst LTC residents have been classified into three categories: social factors (e.g. poverty, social isolation), psychological factors (e.g. depression and dementia), and medical factors (e.g. poor dentition, cardiac failure, infection, multiple medications, dysphagia) (Chapman, 2006). Associations have also been drawn between malnutrition and dementia and swallowing difficulties, amongst other factors (Suominen, 2005; Odlund, Koochek, Liungqvist, & Cederholm, 2005). It has been shown that in geriatric institutions chewing problems, a type of oral dysphagia, is a risk factor for a low BMI or weight loss (Blaum, Fries, & Fiatarone, 1995). Based on these pieces of evidence, it quickly becomes apparent that swallowing disorders may play a key role in the malnourishment of those in LTC. Currently, most interventions that have been reported to either improve or maintain nutritional status fall into one of three groups: changing environmental factors, adding resources for supporting residents during mealtimes, and modifying the food. However, to determine which of these three categories, if any, might be best suited to residents in LTC, it is critical that an adequate understanding of the cause of the problem is established.

**Section 1.03 The Tongue and Dysphagia**

**Section 1.04** It is generally accepted that normal aging is accompanied by decreases in strength and changes in skeletal muscle, which comprises the bulk of the tongue. Loss of skeletal muscle mass around the body generally occurs after the age of 60, due to muscle atrophy and motor neuron loss (Larrson, 1978). The normal process of aging is also associated with muscle-wasting conditions, such as sarcopenia and cachexia, both of which can have an impact on nutritional status. Sarcopenia can be described as an age-related shift in body composition, specifically the loss of muscle mass. Cachexia, which is a complex metabolic syndrome associated with an underlying illness that is characterized by loss of muscle with or without the loss of fat, has also been identified in residents of LTC (Thomas, 2009; Chapman, 2007; Landi, Layiano, & Cruz-Jentoft, 2010). While these changes seen in major muscle groups may also occur in the tongue, there is little evidence that this causes any clinical deficits.

Figure 1. Lateral view of tongue and bolus during the oral phase of swallowing, as seen in a videofluoroscopic examination.
Swallowing involves a series of three phases: oral, pharyngeal, and esophageal. Each of these phases requires several muscles and nerves to be intact in order to facilitate a safe and efficient swallow. Dysphagia, or swallowing impairment, occurs when any of the muscles or nerves involved in swallowing are damaged or become weak, and material from the swallow is entering the airway or there is residue left behind. Medical recovery is negatively impacted by dysphagia, which often causes longer hospitalization and an increased need for LTC (Odderson, Keaton, & McKenna, 1995). A common sequela of dysphagia, aspiration pneumonia, is associated with a significant risk of for morbidity and mortality (Shariatzadeh & Marrie, 2006). Appropriate tongue strength is crucial to help avoid these problems, as it is essential for the oral and pharyngeal phases of swallowing. The tongue contributes to the formation, placement, and manipulation of the bolus within the oral cavity, and propulsion into the pharynx (see Figure 1) (Youmans & Stierwalt, 2006). If any of the eight muscles of the tongue become weak, its functions can easily become hindered. As such, it is important that the implications of a weakened tongue are understood, especially in regards to those who are in LTC and are at risk for malnourishment.

The tongue is a muscular hydrostat (Kier & Smith, 1985), meaning its mechanical effect is dependent upon the integrated activity of the other muscles within the organ (Kairaitis, 2010). Additionally, it is composed of both Type I and Type II muscles fibres. While Type II fibres, those that are fast-twitch and fatiguable, are predominant, the tongue tip is made up of mostly Type I fibres, those that are slow-twitch and fatigue-resistant (Kent, 2004). The anterior portion of the tongue performs more endurance activities, such as talking, so fatigue-resistance is a key feature. If this portion of the tongue were to lose muscle as one ages, it is possible that fatigue may set in faster than usual, inhibiting some portion of the swallowing functions. Identifying more effective methods of diagnosis and treatment has been designated as a top priority in rehabilitation research (Robbins, Langmore, Hind, & Erlichman, 2001), in order to improve the health and quality of life and decrease fatalities in those with dysphagia.

**Section 1.05   Fatigue and Strength of the Tongue**

Muscle fatigue can be described as an acute reduction in the ability to exert muscle force, independent of whether the force can be sustained (Gandevia, 2001). Fatigue is a commonly reported condition in older adults (Poluri, Mores, Cook, Findley, & Cristian, 2005), and has pervasive effects on many activities of daily living, including dining. Older adults who are at risk for or have been diagnosed with dysphagia often report that it takes them longer to eat than others, and swallowing is more difficult at the end of the day (Roy, Stemple, Merrill, & Thomas, 2007). Given the tongue’s role in swallowing, it is conceivable that an age-related reduction in tongue strength increases the physiological demands of mealtimes, consequently reducing one’s overall food intake and contributing to malnutrition over time. In a study of 10 young adults who ate a 1,000 calorie meal, a total of 440 solid boluses were observed, suggesting an average of 44 solid bolus swallows per individual (Dua, Ren Barden, Xie, & Shaker, 1997). These data indicate that the consumption of an entire meal, which demands multiple swallows of various textures, volumes and consistencies, definitely is a strength task that has the potential to induce fatigue.
Many studies have been published on tongue strength on both healthy and disordered populations, but mostly concentrate on speech production rather than swallowing (e.g., Goozee, Murdoch, & Theodoros, 2001; Robin, Goel, Somodi, & Luschei, 1992; Chang, Chen, Ko, & Lin, 2008). Research in the area of tongue strength as it relates to swallowing tasks are only recently emerging. Standard evaluation techniques for potentially dysphagic patients are based on an oral mechanism exam, which subjectively evaluates the strength and function of the muscles and nerves of the oral cavity, as well as swallows performed at the bedside or during an instrumental examination. With these methods, any judgments made about tongue strength may not be accurate. Moreover, judgments about the effectiveness of a treatment strategy, ideally designed to enhance swallowing safety and efficiency, with practical extensions to mealtimes, are based on the immediate outcomes of only several swallows and fail to capture the potential for fatigue over the course of an entire meal. To simulate the demands of a meal experience when decreased strength is expected, Logemann (1998) suggests observing patients instrumentally prior to and after eating a meal. When Kay and colleagues (2010) used this technique to determine if tongue strength in healthy old and young adults, they found that all subject demonstrated reduced tongue strength postmeal. Since it is clear that meal consumption is sufficient to fatigue older, healthy people, it is logical to determine the impact of meal consumption on the elderly living in LTC who have health issues, as they are the segment of the population who are suffering the most from malnutrition. If we can determine if tongue strength is impacting meal consumption, and is contributing to malnutrition, then we can develop interventions to mitigate this problem. In turn, this research will help to improve the quality of life of those in LTC, possibly prolong these residents’ lives, while saving the healthcare system thousands of dollars because of reduced hospital admissions.

Article II. Steering Committee
The principal investigator for M3 is Dr. Heather Keller, and her co-investigators include: Dr. Lisa Duizer, Dr. Susan Slaughter, Dr. Catriona Steele, Dr. Natalie Carrier, and Dr. Christina Lengyel. In addition to these investigators, Ashwini Namasivayam will be a co-investigator on this project as part of her doctoral dissertation work. Dr. Heather Keller will be transferring the data to the University Health Network for Dr. Steele and Ashwini to perform a secondary data analysis.

2. Purpose and Specific Aims
The purpose of this study is to describe whether tongue strength is associated with food intake in elderly residents in a long term care facility. We are proposing to analyze an existing data set of tongue pressure data collected under a study protocol previously approved at the University of Waterloo. Analysis of the data will help us to better understand how tongue strength impacts the length of time taken to eat a meal and the amount of food consumed. We hypothesize that those with reduced tongue strength will take longer to finish eating, will have more mealtime difficulties, and will eat less than those residents whose tongue strength falls within the norms.
3. Methods

Section 2.01 Participants
The data set consists of data already collected from a sample of 80 LTC residents from 4 LTC facilities in Ontario. This data collection was part of a study protocol previously approved at the University of Waterloo. Relevant fields from the database relating to tongue strength and food intake will be transferred to Toronto Rehab for analysis. These data are already deidentified.

Section 2.02 Inclusion Criteria
The main inclusion criteria for participation were as follows:
(1) over the age of 65;
(2) require at least 2 hours per day of nursing care due to dependence in activities of daily living (i.e. bathing);
(3) can follow simple, one-step directions;
(4) have resided in the home for at least 3 months;
(5) either they or their substitute decision maker provide consent to participate.

Section 2.03 Exclusion Criteria
Unit staff identified those meeting the inclusion criteria. Residents were excluded if they:
(1) had been in the care home for less than three months;
(2) were medically unstable (i.e., >1 month acute care hospitalization);
(3) were on a short term admission (e.g. respite);
(4) required tube-feeding;
(5) were not eating because they are end of life;
(6) had advanced directives that excluding them from research.

Section 2.04 Recruitment
Eligible residents from the units selected for data collection were randomly sampled to attain the home’s quota of 20-25 participants. Age, gender, activities of daily living, and cognition (Cognitive Performance Scale from the Minimum Data Set) were noted for all eligible residents, to determine representativeness of participants.

Home staff initially approached those residents randomly selected for participation. If they indicated interest, their name/room number was provided to research staff. In the event that a resident did not have the cognitive capacity to complete their own consent (based on their Minimum Data Set Data, Cognitive Performance Scale), home staff contacted the family substitute decision maker via telephone, using a predefined script, to determine their interest in being approached by research staff to hear more about the research. Once verbal consent was provided to have a researcher speak to the resident and/or family, the researcher made contact and reviewed the procedures with the potential participant/family member. A detailed information letter and written consent form was provided and completed prior to data collection.
Section 2.05 Data Collection

Data were collected at unit and resident levels to describe and identify determinants of inadequate food intake. Time for data collection in each home was driven primarily by the collection of 3 days of food intake data and meal observations for each participant. One month (20 working days) per home was required to collect all data, and this began in January 2015.

For the unit-level data collection, three meals on each participating unit were randomly selected to identify the number and type of staff, family, and volunteers in the dining room. More specifically, the number of eating assistants was noted. Measures were averaged across observations.

For the resident-level data collection, three nonconsecutive days of estimated food intake were collected from all participants. A trained research assistant (RA) weighed each full food tray, including utensils and napkin, before and after the participant ate using a scale. Up to four residents per meal ate in the same dining area and were observed by two trained RAs; residents who ate in their room were accommodated by the inclusion of a third observer. Residents who were away from the home for a meal were not observed on that day. Reference main plates/portions (pureed, minced, regular texture) were weighed at the beginning of meal service; observers noted by estimation if offered food was different in portion size from the reference (i.e., a half portion). RAs also used a timer to determine the length of time for each of the participants to complete eating their meals.

Determination of malnutrition was needed to characterize the population and be considered as a potential covariate in analyses. The Mini Nutritional Assessment – Short Form ® (MNA-SF) (Appendix I) was used for this portion of the data collection. This short-form screening tool includes body mass index, weight loss, calf circumference, and functional parameters accessed from the health record. Seated or supine knee height was used to estimate standing height using valid equations (Hickson & Frost, 2003). Body weight were measured with standardized procedures (Niezgoda, Trainor, Chambers, Keller, & Caissie, 2011) and body weight history was taken from the health record for the prior six months. Calf circumference was collected using standardized procedures and gender-specific cut-points (Isenring, Banks, Ferguson, & Bauer, 2012). Using a MNA-SF score of ≥11 as normal, this tool has a sensitivity of 97.9% and a specificity of 100%, as well as a diagnostic accuracy of 98.7% for predicting undernutrition (Rubesnstein, Harker, Salva, Guigoz, & Vellas, 2000).

A certified dental hygienist examined the oral structures of the residents. This exam was only completed on residents who could follow commands to open their mouth. The assessment involved the counting of teeth, determination of inflammation/broken/carious teeth, saliva thickness etc. and took a total of 5 minutes.

Resident health records were reviewed for factors (e.g., diagnoses, medication use, ethnicity, gender) required to describe the sample and selected variables will be used in regression analyses. Number of prescribed medications and use of sedatives, psychotropics or antibiotics will be included in analyses. Current infection which may impair food intake will be determined using consensus guideline criteria specific to LTC populations (e.g., signs and symptoms) (Stone et al., 2012).
Measures of tongue strength were taken using the *Iowa Oral Performance Instrument* (IOPI). The IOPI is a handheld pressure bulb system that consists of a small air-filled bulb (see Figure 2) that senses pressure when squeezed between the tongue and the hard palate. In consultation with the manufacturer, we have developed a LabView software program to register a digital pressure waveform from the analog signal generated by the IOPI at 250 Hz (see Figure 3); this enables us to provide a biofeedback screen view of the tongue pressure measurement to the participant during data collection, and to extract detailed measures of tongue pressure amplitude and timing. Maximum isometric tongue pressure were recorded across a series of three bulb squeezes, with the bulb held in an anterior position, just behind the teeth (see Figure 4). A value of 55kPa of greater will be considered normal for the population of interest in this study, whereas anything lower than 55kPa will be considered weak (Stierwalt & Youmans, 2007). Additionally, saliva swallows were recorded across a series of 3 cued tasks, with the bulb held the same anterior position. Tongue pressure tasks were cued with a 10 second rest between each task repetition. In total, 2 minutes were required to collect the tongue pressure measures. A clean, individually wrapped, single-use tongue pressure bulb was used for each participant, and disposed of immediately after use.

Figure 4. IOPI anterior bulb placement.

Section 2.06

Section 2.07 Data Analysis

After completion of the nutrition, oral health and dysphagia screenings, as well as the tongue pressure tasks and the mealtime observations, data were labeled with a non-identifying study code number and saved to a secure, password-protected, encrypted data base on the research server.
The effect of tongue strength on meal consumption for residents in long term care will be determined using a one-way analysis of variance (ANOVA) with a factor of tongue strength (< 40kPa or > 40kPa, where a value of 40kPa or above is being considered normal), and a repeated factor of meals (1-9).

4. Risks and Benefits
Residents, as part of this pilot, underwent a detailed nutrition assessment, including screening for swallowing challenges. Findings could result in improved care as these will be communicated back to professional staff at the home as well as the resident or alternate decision maker.

Results of this study will provide a comprehensive understanding of the key influencers of food intake. A program of research focused on development of interventions, their implementation and evaluation are planned. Knowledge translation concerning the issues associated with food intake in LTC will result and will provide the necessary data to support further research and practice change in this area.

There were minimal risks associated with the study. All physiological measurements conducted with residents were a part of routine quality nutrition care. A standardized swallowing challenge with small sips of water and applesauce was used for all residents, excepting those consuming thickened fluids. The only potential risk with this assessment was the potential aspiration of small amounts of food/fluid, which exists on their current diets. None of the residents experienced adverse effects due to aspiration. The only risks anticipated with mealtime observations were the feeling that residents are being 'selected out' at mealtimes, but this was not an issue. The only other potential risk was that of research burden for participants due to the number of measures/assessments; no complaints of this nature were made.

While conducting the tongue pressure tasks there were a few risks to participants. These risks included choking and allergic reaction to the materials being used, but these were no greater than the risks already present at mealtime for all participants. The speech-language pathologist who carried out the data collection had current cardiopulmonary resuscitation certification, and emergency services were available onsite in the unlikely event of a patient arrest. No adverse events occurred during the collection of the tongue pressure tasks.

5. Privacy and Confidentiality
All data has been stored on a computer for offline analysis. Information gathered from participants has been kept confidential and identified using a set of unique alphanumeric codes. Access to participant information and experimental raw data will be restricted to the investigators named in this proposal. All records will be destroyed after 10 years under the supervision of Dr. Steele.

6. Compensation
There was no compensation for participation.
7. **Conflicts of Interest**
Neither Dr. Steele nor Ashwini Namasivayam have any conflicts of interest to disclose.

8. **Scholarly Review**
This study has previously undergone scientific review through the University of Waterloo.

9. **Additional Ethics Reviews**
The M3 study has been approved by the ethics board at the University of Waterloo.

10. **Contracts**
A data transfer agreement has been made between the University of Waterloo and the University Health Network.

11. **Clinical Trials**
Not applicable.

12. **Budget**
All costs for this study were covered the CIHR Operating grant that was obtained for the full M3 study by Dr. Heather Keller at the University of Waterloo. Dr. Catriona Steele is a co-investigator on this study and grant.

13. **References**


Kairaitis, K. (2010), Is the pharynx a muscular hydrostat?. Medical Hypotheses. 74(3), 590-595


Appendix I: Mini Nutritional Assessment – Short Form

### Mini Nutritional Assessment

**Last name:**

**First name:**

**Sex:**

**Age:**

**Weight, kg:**

**Height, cm:**

**Date:**

#### Screening

**A** Has food intake declined over the past 3 months due to loss of appetite, digestive problems, chewing or swallowing difficulties?
- 0 = severe decrease in food intake
- 1 = moderate decrease in food intake
- 2 = no decrease in food intake

**B** Weight loss during the last 3 months
- 0 = weight loss greater than 3 kg (6.6 lbs)
- 1 = not known
- 2 = weight loss between 1.5 and 3.5 kg (2.2 and 6.6 lbs)
- 3 = no weight loss

**C** Mobility
- 0 = bed or chair bound
- 1 = able to get out of bed / chair but does not go out
- 2 = goes out

**D** Has suffered psychological stress or acute disease in the past 3 months?
- 0 = yes
- 2 = no

**E** Neuropsychological problems
- 0 = severe dementia or depression
- 1 = mild dementia
- 2 = no psychological problems

**F1** Body Mass index (BMI) (weight in kg) / (height in m²)
- 0 = BMI less than 19
- 1 = BMI 19 to less than 21
- 2 = BMI 21 to less than 23
- 3 = BMI 23 or greater

**F2** Calf circumference (CC) in cm
- 0 = CC less than 31
- 3 = CC 31 or greater

#### Screening score

(max 14 points)

<table>
<thead>
<tr>
<th>12-14 points:</th>
<th>Normal nutritional status</th>
</tr>
</thead>
<tbody>
<tr>
<td>8-11 points:</td>
<td>At risk of malnutrition</td>
</tr>
<tr>
<td>0-7 points:</td>
<td>Malnourished</td>
</tr>
</tbody>
</table>

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For more information: www.mna-elderly.com
CONSENT FORM

Making the Most of Mealtimes
Determinants of Food Intake in Long Term Care

I have read the information letter describing the project entitled: “Making the Most of Mealtimes Determinants of Food Intake in Long Term Care” being conducted by Professor Heather Keller at the University of Waterloo. I understand the nature of this project and am providing my consent for my loved one to participate, with the understanding that the final decision to participate rests with him/her. I have had the opportunity to ask questions about my loved one’s involvement in this study, and have received satisfactory answers to these questions.

I am aware that:

• I may withdraw my consent without penalty at any time by advising the researchers of this decision. My decision to withdraw from the study will not jeopardize my (or my loved one’s) relationship with NAME OF HOME
• by signing this form, I am not waiving any of my (or my loved one’s) legal rights and am not releasing the investigator(s) or involved institution(s) from their legal and professional responsibilities
• If I have any questions about this project, I can contact Professor Heather Keller (519.888.4567 ext. 31761; hkeller@uwaterloo.ca) at any time

This project has been reviewed by, and received ethics clearance through a University of Waterloo Research Ethics Committee.

I was informed that if I have any comments or concerns resulting from my participation in this study, I may contact Dr. Maureen Nummelin (Director, Office of Research Ethics) at any time (519.888.4567 ext. 36005; maureen.nummelin@uwaterloo.ca).
I am aware that selected information from my family member’s medical chart (medications, diagnoses, body weight, diet prescription, and any recent symptoms that can influence food intake) will be collected by research personnel.

I agree to allow research personnel access to my family member’s medical chart. □ YES □ NO

I am aware that nursing staff will be asked to provide information about the health and care of my loved one.

I agree to allow research personnel to discuss aspects of my loved one’s health and care with nursing staff □ YES □ NO

With full knowledge of all foregoing, I agree, of my own free will, to have my loved one participate in this study.

**Alternate Decision Maker**

Name: ____________________
(please print)

Signature: ____________________ Date: ____________________

Name of Witness: ____________________
(please print)

Signature: ____________________ Date: ____________________
Making the Most of Mealtimes

Determinants of Food Intake in Long Term Care

PURPOSE OF PROJECT

Professor Heather Keller at the University of Waterloo is leading a national study looking at characteristics (including swallowing/chewing problems, health status, etc.) that influence food intake in long-term care homes.

SIGNIFICANCE OF THE WORK AND THE NEED FOR THE STUDY

Many factors influence food intake in long-term care, such as the food, the dining atmosphere and the training of staff. At this point, it is unclear which of these factors is the most important and should be the targets for change and improvement. This study is designed to measure a wide range of factors and tease out those that are most important to food intake.

WHO IS ELIGIBLE TO PARTICIPATE IN THE STUDY

Any resident who lives at NAME OF HOME is eligible to participate as long as they:

- are over the age of 65 years;
- have lived at HOME NAME for 1 month;
- speak English; and
- volunteer to participate.
Residents are not eligible to participate if they:

- are medically unstable;
- do not live at NAME OF HOME permanently (i.e., respite care, etc.);
- require tube feeding; or
- are in the final stages of life

WHAT WILL YOUR LOVED ONE BE ASKED TO DO?

If you choose to allow your family member to participate, he/she will be asked to:

6. Allow the researchers to use some basic information from their medical record. Specifically, their age, gender, ethnicity, diagnoses, medications, weight history, diet prescription, use of any nutritional supplements and any recent infections or gastrointestinal symptoms (such as nausea) that could influence food intake. The researcher accessing this information will be a health professional and will only access these portions of their chart. She will have signed a confidentiality agreement and will be made aware of NAME OF HOME policies and procedures around privacy and confidentiality. Researchers will also communicate with nursing staff about your loved one’s current health to ensure that they have the most up to date information on their care.

7. Allow a health professional to complete an assessment of their body composition by observing his/her muscles and body fat, as well as measuring his/her height (estimated from knee height), arm length and calf circumference. Nursing staff will be asked to report on any recent changes in food intake and factors that influence food intake. A body weight will be taken by nursing staff on a bath day.
8. Allow a dental hygienist to examine his/her mouth and teeth for any potential problems. If your loved one is not able to follow commands, such as to open their mouth, the assessment will be stopped.

9. Participate in a swallowing screening test with a Registered Dietitian and speech pathologist that involves taking small sips of water from a cup and eating small spoonfuls of applesauce). Tongue strength will also be determined by putting a new, sterile thumb sized balloon on the tip of the tongue and your loved one will be asked to squeeze this to the top of their mouth for 2 seconds. If they are unable to follow commands, neither of these assessments will be completed. If they are on thickened fluids, this examination will not be done.

10. Have their mealtime experience observed in the dining room and their food intake monitored for three days by weighing the main plate and asking nursing about food consumption between meals.

HOW MUCH TIME WILL THIS PROJECT TAKE?

Outside of meal observations that do not require “active” participation, your loved one will spend approximately a 1/2 hour with the research team to collect information. In order to minimize fatigue, testing will be spread out over more than one visit.

WHAT ARE THE POTENTIAL BENEFITS ASSOCIATED WITH PARTICIPATION?

This is the first study of its kind in the world and will provide a strong basis for making changes to support food intake, health and quality of life of long-term care residents.

We will provide you with a thank you letter at the end of the study. Contact information of the researchers will be on this letter if you wish to receive a final report. If the research team uncovers any potential health concerns, the dietetic staff at NAME OF HOME will receive an individualized report so that your love one’s needs can be followed up appropriately.

ARE THERE ANY RISKS ASSOCIATED WITH PARTICIPATION?
There are no risks associated with this study. All measures are part of standard practice. Data collection will be conducted in private where possible. For residents who require thickened fluids, the swallowing screening test will not be done.

**WHAT HAPPENS IF I WANT MY LOVED ONE TO WITHDRAW FROM THE STUDY?**

Your loved one’s participation is voluntary and you may decide to stop participation in the study at any time by informing Professor Keller. The care your loved one receives now or in the future through this or any other health care facility will not be affected by your decision to allow him/her to participate or to withdraw from the study. Please note that the research team will ask your loved one if he/she would like to participate prior to conducting any direct measures or observations. Even if you provide consent for the research team to approach your loved one, the final decision about participation rests with your loved one.

**WHAT PROCEDURES ARE IN PLACE TO ENSURE CONFIDENTIALITY?**

The data collected in this study will be kept confidential. Each participant will be given a participant code that will be used to identify their assessment results. All data will be encrypted and any information that identifies participants will be destroyed at the end of the study. Where a potential health risk is uncovered as a result of the assessment, dietetic staff at NAME OF HOME will be provided with this information for appropriate follow-up.

Any publications or reports that result from this study will present group data and your loved one’s information will not be identifiable. Coded information will be encrypted stored in locked offices and on secure computers at the University of Waterloo and may be retained indefinitely.

**WILL RESIDENTS BE PAID FOR PARTICIPATING IN THE PROJECT?**

Participants will not be paid for their participation in the project.

**HOW WILL I LEARN ABOUT THE RESULTS OF THE PROJECT?**
You will receive a thank you letter at the end of data collection in this home. If you are interested in receiving a report of the entire study, you can contact the researchers who will send you a short report of key findings.

**WHO CAN I CONTACT IF I HAVE QUESTIONS?**

If you have any questions about your participation in this project, please contact the Primary Investigator Professor Heather Keller at any time (519.888.4567 ext. 31761; hkeller@uwaterloo.ca).

**HAS THE PROJECT RECEIVED CLEARANCE FROM A RESEARCH ETHICS BOARD?**

This project has been received ethics clearance through a University of Waterloo Research Ethics Committee. If you have any comments or concerns resulting from your loved one’s participation in this study, you may contact Dr. Maureen Nummelin (Director, Office of Research Ethics) at any time (519.888.4567 ext. 36005; maureen.nummelin@uwaterloo.ca).
STUDY PROTOCOL

TONGUE STRENGTHENING INTERVENTION IN LONG TERM CARE

PI: Catriona M. Steele, Ph.D.

Swallowing Rehabilitation Research Laboratory

Toronto Rehabilitation Institute – University Health Network
14. Introduction

Malnutrition, defined as an inadequacy or imbalance in energy and/or nutrients to meet the body’s functional needs [1], occurs in more than half of residents living in long term care (LTC) (i.e., residences where two or more hours per day of nursing care are provided, also called nursing homes) (e.g., [2-9]). Consequences of LTC malnutrition include: infections; falls; pressure ulcers; declines in function and cognition; hospital admissions; extended lengths of stay in hospital; and death (e.g., [10 - 13]). These outcomes are costly to the system, both in terms of health care and patient flow. LTC residents are a relatively small proportion of the 65 and over age group, yet they account for approximately 10% of all acute care admissions in Canada [14]. When residents return to their LTC home after hospitalization they are often more confused and functionally impaired. Poor food and fluid intake is the primary cause for LTC malnutrition; average consumption has been estimated at 50% of food offered [15]. LTC malnutrition is both preventable and treatable. Interventions that promote food consumption are also likely to improve the health and function of residents.

As age increases, the risk of dysphagia also increases. Dysphagia is a term used to describe swallowing impairment, regardless of etiology. Dysphagia is common in individuals who have neurological diagnoses (stroke, brain injury, Parkinson’s disease, etc.), as well as following head and neck cancer. Moreover, some physiological changes in swallowing are reported to occur as part of healthy aging (presbyphagia). For example, age-related functional changes in muscle activity include longer muscle activity (twitch prolongation) in the head and neck [16, 17], as well as slower waveforms of the pharyngeal constrictors and lower resting tone of the upper esophageal sphincter [18, 19]. Age-related diminishment in strength, mobility and endurance is also evident in the tongue [20, 21]. Regardless of etiology, swallowing impairment places a person at risk of reduced nutritional intake [22-24]. In particular, dysphagia is also a known comorbidity of dementia [25]. According to the Alzheimer Society of Canada [26], approximately 747,000 Canadians currently have some type of dementia and more than 200,000 of these people reside in LTC. When present, dysphagia predisposes individuals with dementia to dehydration, malnutrition, weight loss, and aspiration pneumonia [27 -29].

Given that both aging and dementia increase the risk of having dysphagia, and that dysphagia can lead to malnutrition, it is logical to explore the associations between these conditions. Due to the fact that self-feeding is not always adequately supported in LTC and eating assistance can be limited, residents with dysphagia may be particularly prone to inadequate food intake. Further, their intake might also be affected by overall fatigue, as this is a commonly reported condition of older adults [30]; this could contribute to reduced food intake [31]. Considering that the muscles of the tongue are active participants in the swallowing process, it would be expected that as fatigue sets in, the strength of these muscles will decline and eating may become a more arduous task, which could lead to reduced ingestion, contributing to malnutrition over time.
15. **Steering Committee**

In addition to the PI, Ashwini Namasivayam will be a co-investigator on this project as part of her doctoral dissertation work. Together, Dr. Steele and Ashwini will form the steering committee for this project.

16. **Purpose and Specific Aims**

The most common intervention for swallowing difficulties is to prescribe thickened liquids [32]. Yet, thickened liquids are reported to be unpalatable for most people, and patients receiving thickened liquids are prone to dehydration [33-36]. Consequently, it is important that dysphagia researchers explore treatments that allow patients to drink safely and enjoy thin liquids. Several studies have explored tongue pressure training as an intervention for reduced tongue strength in various populations, including healthy individuals, those with dysphagia after stroke, and dysphagia after acquired brain injuries. Robbins ([37, 38]) and Steele et al. ([39, 40] have shown that resistance training can be used to improve tongue strength (maximum isometric tongue pressures) in healthy seniors and dysphagia following stroke and acquired brain injury. However, tongue pressure training has not been explored in the LTC population or in individuals in the early stages of dementia. Given that low tongue pressures in LTC residents appear to be associated with increased mealtime difficulties, increased length of time to eat a meal and reduced food consumption [41], improving tongue strength may help to reduce the impact of dysphagia, promote better mealtime function and nutritional intake.

If the need for diet texture modifications can be deferred through the use of a tongue strength training intervention, the quality of life for residents in LTC may improve and the risk of malnutrition may decrease. In this research, we hypothesize that a tongue pressure resistance training protocol will yield improvements in measures of mealtime food consumption and tongue fatigue for elderly residents in LTC with low tongue strength. We propose to test this hypothesis in a small, prospective sample of elderly residents living in LTC with low tongue strength pressures. Our goal is to collect preliminary evidence of treatment outcomes in LTC residents with a tongue pressure training protocol historically used in stroke patients, in comparison to a no treatment control group.

17. **Methods**

**Section 2.08 Participants**

A prospective series of 8 long term care residents will be enrolled based on evidence of low MIPs (under 40 kPa anteriorly and/or posteriorly).

**Section 2.09 Inclusion Criteria**

The main inclusion criteria are as follows:

1. over the age of 65;
2. require at least 2 hours per day of nursing care due to dependence in activities of daily living (i.e. bathing);
(3) can follow simple, three-step directions;
(4) have resided in the home for at least 3 months;
(5) are able to drink thin liquids and eat regular textures;
(6) either they or their substitute decision maker provide consent to participate;
(7) can commit to 6-8 weeks of the intervention;
(8) have reduced tongue strength (> 40kPa).

Section 2.10 Exclusion Criteria
Unit staff will identify those meeting our inclusion criteria. Residents will be excluded if they:
(1) have been in the care home for less than three months;
(2) are currently medically unstable (i.e., >1 month acute care hospitalization);
(3) are on a short term admission (e.g. respite);
(4) require tube-feeding;
(5) have been prescribed thickened liquids;
(6) are not eating because they are end of life;
(7) have advanced directives that excluding them from research;
(8) are on a texture modified diet.

Section 2.11 Recruitment
Recruitment of participants will be conducted in one of two ways:

a) A booth will be set up at Lakeside over 2-3 days beginning at lunch hour, and extending until dinner time, where residents, staff and visitors will have the opportunity to get their tongue strength tested, if interested. Any resident with low tongue strength (less than 40kPa) will be given a flyer explaining more about the study (Appendix A). For those who show an interest, a study team member will be available to hold a brief discussion with the resident, at which time it will be confirmed if the resident fits the remainder of the inclusion criteria (#1-7). For those residents who appear interested in participating, a formal information and consent session will be scheduled.

b) Staff at Lakeside will be asked to identify residents who fit inclusion criteria #1-7 and make an initial approach to see if they would be interested in the study. If interested, the staff will request permission to give the resident’s name to a member of the research team so that an intake session can be scheduled to discuss the study and confirm eligibility (including measurement of tongue strength). Residents who qualify will be given an information and consent sheet to look over.
Section 2.12 Study Design

This is a randomized multiple baselines study. Participants will be “randomized” into one of the study groups described below. Participants will have a 50/50 chance of being placed in either group, and will be told immediately which group they are in.

- Participants in group A will be observed at six meals before beginning 16 sessions of therapy. These mealtime observations involve having a research assistant observe the resident while they eat regularly scheduled meals in the dining room two times in one week. This procedure will be repeated twice more, with the observations scheduled approximately two weeks apart. The therapy sessions will then begin 2-3 times a week for approximately 8 weeks, until 16 sessions have been completed. Another set of two mealtime observations will be completed after therapy is complete.

- Participants in group B will be observed at ten meals before beginning 16 sessions of therapy. These mealtime observations involve having a research assistant observe them while they eat regularly scheduled meals in the dining room two times in one week. This procedure will be performed a total of five times, with the observations scheduled approximately two weeks apart. The therapy session will then begin 2-3 times a week for approximately 8 weeks, until 16 sessions have been completed. Another set of mealtime observations will be completed after therapy is complete.

All participants will receive the same tongue exercise program.

The purpose of this study is to test the efficacy of a tongue strengthening intervention protocol in the long term care population.
Section 2.13   Data to be collected from each participant:
The following types of data will be collected from participants:

a) An intake questionnaire noting age, sex and confirming eligibility based on the inclusion and exclusion criteria.

b) Tongue-pressure waveform data, collected at the anterior and posterior palate using the Iowa Oral Performance Instrument (IOPI) during each of the 16 intervention sessions. Screening for low tongue pressures will be conducted prior to the first mealtime observation using the IOPI. Individual tongue strengthening intervention sessions (40-60 minutes) will be conducted by a licensed speech-language pathologist and will take place 2-3 times per week. Sessions will involve strengthening the tongue through tongue presses and saliva swallows. Each session will contain 60 tongue-pressure resistance tasks.

c) Measurement of functional mealtime outcomes will be derived from scores on the Edinburgh Feeding Evaluation for Dementia (EdFED) questionnaire, based on three or five (depending on the group) baseline mealtime observations, compared to a post-treatment mealtime observations. RAs will enter the dining area for observations before the scheduled start of the meal.

d) Time to eat for residents will be recorded as the duration of time when the resident was at their table and there was food and/or fluid in front of them for consumption. Similarly, the end of meal will be captured as the time when the resident leaves the dining area and does not return OR when no food/fluid remains in front of the resident.

e) Amount of food eaten will be determined by weighing each resident’s food tray with a kitchen scale prior to each resident eating their meal and after each resident has finished their meal.

Section 2.14   Data Analysis
Single-subject descriptive methods will be used to report treatment progress for the tongue pressure parameters, which will be probed at each treatment sessions. A control chart method with effect-size banding will be used to confirm the presence or absence of change as follows:

1. Measures of baseline tongue pressure range, by task, will be computed using mean and standard deviation values for each participant for all maximum isometric tongue pressure tasks across the first three treatment sessions. This range will constitute the baseline reference range to which subsequent data will be compared.

2. Means and standard deviations for tongue pressure amplitudes will be calculated separately by task from the IOPI data collected during each session. These values will be plotted on control charts to document change in tongue pressure parameters over time.
3. An effect size band of Cohen’s $d = \pm 0.6$, i.e., a strong effect, will be established around the baseline mean values and plotted using dashed lines above and below the baseline reference range on the control charts.

4. An a priori criterion for concluding that change in maximum isometric pressure values has occurred will be established as evidence of three or more consecutive data points falling outside the effect-size band boundaries.

Measurement of functional mealtime outcomes will be derived from scores on the Edinburgh Feeding Evaluation in Dementia based on baseline and post-treatment mealtime observations. A paired t-test will be used to compare pre- and post-treatment scores.

18. Risks and Benefits

This study could benefit participants as they may be able to defer to the transition to texture modified diets by strengthening their tongues and reducing the incidences of mealtime difficulties.

There are a few risks to participants in this study. These risks include choking and allergic reaction to the materials being used, but these are no greater than the risks already present at mealtime for all participants. The speech-language pathologist who will be carrying out the data collection has current cardiopulmonary resuscitation certification, and emergency services are available onsite in the unlikely event of a patient arrest. Any such events will be documented according to facility incident reporting requirements. It should be noted that we have conducted swallowing experiments using similar procedures in the Swallowing Rehabilitation Research Laboratory (SRRL) at Toronto Rehab for the past 6 years without any occurrence of serious adverse events.

19. Privacy and Confidentiality

Routine practices for ensuring the confidentiality and privacy of all participants will be followed in this study. All research personnel at the Toronto Rehabilitation Institute are required to sign a confidentiality agreement at the time of hire. Participants will be assigned a non-identifying alphanumeric study code, and the master key for this code will be retained separately by the Principal Investigator in a password-protected file on a secure, password-protected, encrypted research server. Daily back-up of this research server is performed centrally at the Toronto Rehabilitation Institute to protect against data loss. Hard copies of the participant consent forms will be maintained in a binder, kept in a locked filing cabinet in the Swallowing Rehabilitation Research Lab.

All waveform data will be stored electronically on the secure, password protected, encrypted research server. Any hard copy data will be transcribed into an electronic file (stored on the server), and the hard copy records will be stored in a locked filing cabinet in the Swallowing Rehabilitation Research Lab. Only the participant’s alphanumeric study code number will appear on the data collection sheets and in the data collection files.
Access to participant information and experimental raw data will be restricted to the study personnel named in this application. All records will be destroyed after 10 years under the supervision of Dr. Steele.

20. **Compensation**
Given that the study is time consuming, participants will be given a $100 gift card to Shoppers Drug Mart if they complete all necessary components of the study. For those who do not complete the full study but complete at least half (8 intervention sessions) a $50 Shoppers Drug Mart gift card will be given.

21. **Conflicts of Interest**
Neither Dr. Steele nor Ashwini Namasivayam have any conflicts of interest to disclose.

22. **Informed Consent Process**
All participants who show an interest in participating will be provided with detailed information about this study via the Participant Information Sheet and Consent Form (Appendix B) two weeks prior to the scheduled intake session. Only after confirming they have understood all the information that is provided and after verifying they have no more questions, can they sign the consent form (Appendix B). A copy of the consent form will be provided to them. When the ability to comprehend the study is in question we will also request assent from the patient’s substitute decision maker prior to enrolling a patient in the study.

23. **Scholarly Review**
This study has not undergone scientific review anywhere else.

24. **Additional Ethics Reviews**
There are no additional ethics reviews planned for this protocol.

25. **Contracts**
There are no contracts required for this protocol, as it will be conducted exclusively at the Toronto Rehabilitation Institute.

26. **Clinical Trials**
Not applicable.


27. Budget
All costs for this study will be covered through internal funding, more specifically money from the Toronto Rehabilitation Institute Swallowing Team fund.

- Iowa Oral Performance Instrument disposable bulbs (150 x $5) $750.00
- Research assistants for meal observations (2 x 80 hours x $20/hour) $3200.00
- Mileage for research assistants from Kitchener (2 x 206 km x 10 visits x 0.40 cents/km) $1648.00
- Shoppers Drug Mart Gift Gards (8 x $100 - $630) $170.00

[$630 worth of gift cards are leftover from a previous study]

TOTAL $5768.00

28. References


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26. Alzheimer Society. A new way of looking at the impact of dementia in Canada
The Swallowing Rehabilitation Research Lab at Toronto Rehab is running a study to strengthen the tongue and improve mealtime fatigue.
We are looking for Lakeside residents, **65 and older and able to drink thin liquids**, to participate in 16 treatment sessions (2-3 visits per week for an hour), plus mealtime observations, with compensation.

Please contact Shaista Durrani if interested.

**Article III. CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY**

**Study title:**

Tongue Pressure Strengthening for Residents in Long Term Care.

**Principal Investigator:**

Catriona Steele, Ph.D.
Research Scientist, Toronto Rehabilitation Institute
Phone: 416-597-3422, extension 7603
Fax: 416-597-7131

**Co-Investigator/Contact Person:**

Ashwini Namasivayam, PhD(C), SLP(C), Reg. CASLPO
Speech-Language Pathologist, Research Associate II
Toronto Rehabilitation Institute, University Health Network
Phone: 416-597-3422, extension 7796

E-mail: Ashwini.Namasivayam@uhn.ca
Please note that the security of e-mail messages is not guaranteed. Messages may be forged, forwarded, kept indefinitely, or seen by others using the internet. Do not use e-mail to discuss information you think is sensitive. Do not use e-mail in an emergency since e-mail may be delayed.
**Introduction**

In this consent form, “you” always refers to the study participant. If you are a substitute decision maker (a substitute decision maker (SDM) is someone who makes the decision of participation on behalf of the patient or resident), please remember that “you” refers to the study participant. If the resident regains the capacity to consent for him/herself, your consent for them will end. If at any time during the study, the person becomes capable of providing consent, this consent form will be reviewed with him/her before continuing with his/her participation. This consent form is intended for the person who is eligible to participate in the study.

You are being asked to take part in a research study. Please read the information about the study presented in this form. The form includes details about the study’s risks and benefits that you should know before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask the study principal investigator or study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish including your friends, family, and family doctor. Participation in this study is voluntary.

**Background/Purpose**

The aim of the study is to test a treatment technique for tongue weakness in people who are at risk for swallowing difficulties living in long term care. Currently, if a long term care resident has difficulty swallowing, their diet is modified to include textures that are easier to swallow (like thickened liquids and purees). Our hypothesis is that we could delay the need for diet texture modification by strengthening the tongue in people who are at risk for developing swallowing difficulties.

The study treatment involves exercise for your tongue, and emphasizes your ability to generate tongue pressure. This treatment has previously been used for people with swallowing difficulties after a stroke or acquired brain injury. The findings of these previous studies have shown that exercises are effective for strengthening the tongue and reducing the severity of swallowing difficulties.

The purpose of this study is to determine whether a tongue strengthening treatment is beneficial in the long term care population.

You are being asked to participate because you have volunteered or because the staff at Lakeside have determined that you meet the criteria to participate. This means that you are not currently on a modified texture diet that includes thickened liquids but may be showing some signs of swallowing difficulty at mealtimes.

As mentioned previously, the usual treatment for swallowing difficulties is to modify your diet to include things like thickened liquids. We want to see if we can prevent the need to modify your diet
through a program of tongue exercise. We are also interested to see whether this exercise will reduce the difficulties you experience at mealtimes.

The tongue strengthening intervention is experimental. Experimental means that the tongue strengthening intervention is not used routinely in patient/resident care.

Up to 8 people will participate in this study. All participants will be residents at Lakeside. The study will take 6 months to complete. In our previous research, more than 20 people have received a similar tongue strengthening intervention, and the majority of these people experienced improved swallowing outcomes post-treatment.

This research is being conducted as part of Ashwini Namasivayam’s doctoral dissertation at the University of Toronto.

**Study Design**

This is a randomized multiple baselines study. If you decide to participate you will be “randomized” into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. Neither you nor Lakeside staff can choose what group you will be in. You will have a 50/50 chance of being placed in either group. You will be told immediately which group you are in. All participants will receive the same tongue exercise program. The purpose of this study is to test the efficacy of a tongue strengthening intervention protocol in the long term care population.

- **If you are in group A**, you will be observed at six mealtimes before beginning 16 sessions of therapy. These mealtime observations involve having a research assistant observe you while you eat during regular scheduled mealtimes in the dining room twice in one week. This procedure will be performed three times, with the observations scheduled approximately two weeks apart. The therapy sessions will then begin 2-3 times a week for approximately 8 weeks, until 16 sessions have been completed. Another 2 mealtime observations will be completed after therapy is complete.

- **If you are in group B**, you will be observed at ten mealtimes before beginning 16 sessions of therapy. These mealtime observations involve having a research assistant observe you while you eat regularly scheduled meals in the dining room twice in one week. This procedure will be performed five times, with the observations scheduled approximately two weeks apart. The therapy session will then begin 2-3 times a week for approximately 8 weeks, until 16 sessions have been completed. Another set of mealtime observations will be completed after therapy is complete.
8 LTC residents on regular diets

Screening for low tongue strength

Randomization

**Group A**
- First measurement: 2 meal observations
- 2 week break
- Second measurement: 2 meal observations
- 2 week break
- Third measurement: 2 meal observations
- 16 treatment sessions 2-3 times/week

**Group B**
- First measurement: 2 meal observations
- 2 week break
- Second measurement: 2 meal observations
- 2 week break
- Third measurement: 2 meal observations
- 2 week break
- Fourth measurement: 2 meal observations
- 2 week break
- Fifth measurement: 2 meal observations
- 16 treatment sessions 2-3 times/week

Final measurement: 2 mealtime observations
**Study Visits and Procedures**

For the purposes of this study, all study visits will take place at Lakeside Long Term Care, so participants will not have to travel or incur any travel costs. The following visits will take place:

<table>
<thead>
<tr>
<th>Group A</th>
<th>Group B</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intake session:</strong> Review study documents and consent, discuss health history, measure tongue strength (approximately 30 minutes)</td>
<td><strong>Intake session:</strong> Review study documents and consent, discuss health history, measure tongue strength (approximately 30 minutes)</td>
</tr>
<tr>
<td><strong>Visit 1:</strong> Two meal observations (each approximately 1 hour)</td>
<td><strong>Visit 1:</strong> Two meal observations (each approximately 1 hour)</td>
</tr>
<tr>
<td><strong>Visit 2:</strong> Two meal observations (each approximately 1 hour)</td>
<td><strong>Visit 2:</strong> Two meal observations (each approximately 1 hour)</td>
</tr>
<tr>
<td><strong>Visit 3:</strong> Two meal observations (each approximately 1 hour)</td>
<td><strong>Visit 3:</strong> Two meal observations (each approximately 1 hour)</td>
</tr>
<tr>
<td><strong>Visits 4-19:</strong> Tongue strengthening intervention (each session approximately 45 minutes)</td>
<td><strong>Visit 4:</strong> Two meal observations (each approximately 1 hour)</td>
</tr>
<tr>
<td><strong>Visit 20:</strong> Two meal observations (each approximately 1 hour)</td>
<td><strong>Visit 5:</strong> Two meal observations (each approximately 1 hour)</td>
</tr>
<tr>
<td><strong>Visits 6-21:</strong> Tongue strengthening intervention (each session approximately 45 minutes)</td>
<td><strong>Visit 22:</strong> Two meal observations (each approximately 1 hour)</td>
</tr>
</tbody>
</table>

**Intake Session**

In this short meeting, we will review the research study with you and answer any questions that you have. Once you are comfortable to proceed, and have signed the consent form, we will ask you some brief questions about your health history to make sure that there are no situations like allergies that suggest that you should not participate.

We will also take some measures of your tongue strength and pressure control using a hand-held pressure meter and a small air-filled plastic bulb (see the picture on the right). You will be asked to put the bulb in your
mouth, and squeeze the bulb against the roof of your mouth. We will take measurements during tongue squeezes and saliva swallows. We use a new, clean pressure bulb for each person at each appointment in this study, and dispose of it immediately after use.

Mealtime Observations
The meal observations do not require the participants to do anything other than eat their meals as they normally would. Research assistants will observe through the entirety of meal time.

Interventions Sessions
We will ask you to attend a series of 16 tongue pressure treatment sessions. Each session will last about 45 minutes. We will schedule these sessions 2-3 times per week over 6-8 weeks, and will work with you and your health care team to arrange the schedule.

A licensed speech-language pathologist (SLP) will work with you during your treatment sessions. In each session you will use the tongue pressure bulb described above, and will practice tongue squeezes and saliva swallows. We will record your tongue pressures and give you feedback during the session. Over the course of treatment, we expect that your tongue strength will improve, and we hope that that this will lead to improvements in your ability to swallow thin liquids safely.

Medical records will be accessed for the purposes of this study in order to collect information on any pre-existing medical conditions, and to ensure there has been no prior diagnosis of dysphagia (a swallowing disorder).

You will be in this study for approximately 6 months.

Risks
Taking part in this study has risks. Some of these risks we know about. If you are allergic to chemicals, latex or materials used in the dentist’s office we ask you to tell us this and we will suggest that you do not participate in this study.

All the equipment that is used in this study is manufactured according to safety standards for hospital settings. There are no known risks associated with the equipment.

There is also a possibility of risks that we do not know about and have not been seen in humans to date. Please call the study staff if you have any side effects, even if you do not think it has anything to do with this study.

Benefits
We hope that your swallowing will improve as a result of this experimental treatment, but we cannot guarantee this. The results from the study will contribute to the development of appropriate treatment methods for individuals with swallowing difficulties.
Reminders and Responsibilities
It is important to remember the following things during this study:

• Tell the study team about your health history and any medications you are taking as accurately as possible. This will help to prevent risk for you.
• Ask the study team about anything that worries you.
• Tell the study team anything about your health that has changed.
• Tell the study team if you change your mind about being in the study.

Alternatives to Being in the Study:
Unfortunately, there is no treatment alternative for this study. If you are having swallowing difficulties and are do not want to participate in this study, you should notify the staff at Lakeside and request a referral for a swallowing assessment.

If you choose to participate, you will be randomized (assigned by chance), to receive either tongue strength training on one of two schedules.

Confidentiality

Personal Health Information
If you agree to join this study, the study principal investigator and her study team will look at your personal health information and collect only the information they need for the study. Personal health information is any information that could identify you and includes your:

• name,
• year of birth,
• new or existing medical records, that includes types, dates and results of medical tests or procedures.

Your participation in this study will also be recorded in your medical record at this hospital. This is for clinical safety purposes.

Research Information in Shared Clinical Records
If you participate in this study, information about you from this research project may be stored in your hospital file and in the UHN computer system. The UHN shares the patient information stored on its computers with other hospitals and health care providers in Ontario so they can access the information if it is needed for your clinical care. The study team can tell you what information about you will be stored electronically and may be shared outside of the UHN. If you have any concerns about this, or have any questions, please contact the UHN Privacy Office at 416-340-4800, x6937 (or by email at privacy@uhn.ca).

The following people may come to the hospital to look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study is following proper laws and guidelines:
• Representatives of the University Health Network (UHN) including the UHN Research Ethics Board

Any information learned about you during the study will be kept confidential. Neither your name nor any other identifying information will be made available to anyone other than the investigators. All records will be kept securely under the supervision of Catriona M. Steele, Ph.D. Paper records will be kept stored in a secure locked filing cabinet in the Dr. Steele’s office or the Swallowing Rehabilitation Research Laboratory at Toronto Rehabilitation Institute. Computer records will be kept in a secure, password-protected drive on the Toronto Rehab research server, and on a back-up hard drive. Access to the data will be restricted to Dr. Steele and to research personnel working under her direct supervision. All records will be destroyed after a period of ten years.

**Voluntary Participation**

Your participation in this study is voluntary. You may decide not to be in this study, or you may decide to be in the study now, and then change your mind later. You may leave the study at any time without affecting your care. We will share any new information with you that is learned during the study that might affect your decision to stay in the study.

**Withdrawal from Study**

If you leave the study, the information that was collected before you left the study will still be used in order to help answer the research question. No new information will be collected without your permission.

**Costs and Reimbursement**

You will not have to pay for the intervention involved in this study, and you should not incur any expenses. However, to thank you for participating in the study will give each participant a $50 Shoppers Drug Mart gift card if at least 8 sessions of the intervention are completed. A Shoppers Drug Mart gift card valued at $100 will be given to participants who complete all sessions and the final meal observations.

**Article IV. Rights as a Participant**

If you are harmed as a direct result of taking part in this study, all necessary medical treatment will be made available to you at no cost.

By signing this form you do not give up any of your legal rights against the investigators, sponsor or involved institutions for compensation, nor does this form relieve the investigators, sponsor or involved institutions of their legal and professional responsibilities.

**Conflict of Interest**
Researchers have an interest in completing this study. Their interests should not influence your decision to participate in this study.

**Questions about the Study**

If you have any questions, concerns or would like to speak to the study team for any reason, please call:

- Catriona Steele at 416-597-3422 x7603
- Ashwini Namasivayam at 416-597-3422 x7796

If you have any questions about your rights as a research participant or have concerns about this study, call the Chair of the University Health Network Research Ethics Board (UHN REB) or the Research Ethics office number at 416-581-7849. The REB is a group of people who oversee the ethical conduct of research studies. The UHN REB is not part of the study team. Everything that you discuss will be kept confidential.

You will be given a signed copy of this consent form.
**Consent**

This study has been explained to me and any questions I had have been answered. I know that I may leave the study at any time. I agree to the use of my information as described in this form. I agree to take part in this study.

_________________________  _______________________  ___________
Print Study Participant’s Name  Signature  Date

My signature means that I have explained the study to the participant named above. I have answered all questions.

_________________________  _______________________  ___________
Print Name of Person  Signature  Date

**Obtaining Consent**

☐ The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to, and has had any questions answered.

_________________________  _______________________  ___________
Print Name of Witness  Signature  Date

**Relationship to Participant**

☐ Your signature on this form indicates that you are acting as a substitute decision maker for the participant and the study has been explained to you and all your questions have been answered to your satisfaction. You agree to allow the person you represent to take part in the study. You know that the person you represent can leave the study any time.

_________________________  _______________________  ___________
Name of Substitute Decision Maker  Signature  Date

_________________________
Relationship to Participant
## Appendix B: Chapter 3 Post-Hoc Effect Size Calculations

<table>
<thead>
<tr>
<th>Page #</th>
<th>Statistically Significant Finding</th>
<th>p-value</th>
<th>Group Difference</th>
<th>Pooled Standard Deviation</th>
<th>Cohen’s d</th>
<th>Effect Size Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>42</td>
<td>Individuals in the pilot study identified as having swallowing difficulty had significantly lower maximum isometric tongue strength than those with no signs of swallowing difficulty.</td>
<td>&lt;0.05</td>
<td>19.83 kPa</td>
<td>8.31</td>
<td>2.39</td>
<td>large</td>
</tr>
<tr>
<td>43</td>
<td>Individuals in the pilot study with low tongue strength on maximum isometric pressure tasks had significantly longer mealtime durations.</td>
<td>&lt;0.05</td>
<td>19.83 kPa</td>
<td>13.64</td>
<td>1.49</td>
<td>large</td>
</tr>
</tbody>
</table>