



Archived at the Flinders Academic Commons:

<http://dspace.flinders.edu.au/dspace/>

'This is the peer reviewed version of the following article: Murray J, Doeltgen S, Miller M, Scholten I. Does a Water Protocol Improve the Hydration and Health Status of Individuals with Thin Liquid Aspiration Following Stroke? A Randomized Controlled Trial. *Dysphagia*. 2016 Feb 17. [Epub ahead of print]

which has been published in final form at

DOI:

<http://dx.doi.org/10.1007/s00455-016-9694-x>

Copyright © Springer Science+Business Media

New York 2016

Title: Does a water protocol improve the hydration and health status of individuals with thin liquid aspiration following stroke? A randomized-controlled trial

Jo Murray, Dr Sebastian Doeltgen, Professor Michelle Miller & Dr Ingrid Scholten

Abstract

The benefit of water protocols for individuals with thin-liquid aspiration remains controversial, with mixed findings from a small number of randomized controlled trials (RCTs). This study aimed to contribute to the evidence of the effectiveness of water protocols with a particular emphasis on health outcomes, especially hydration. An RCT was conducted with patients with known thin-liquid aspiration post-stroke randomized to receiving thickened liquids only or a water protocol. For the 14 participants in rehabilitation facilities whose data proceeded to analysis, there was no difference in the total amount of beverages consumed between the water protocol group (mean=1103ml per day, SD=215ml) and the thickened liquids only group (mean=1103ml, SD=247ml). Participants in the water protocol group drank on average 299ml (SD 274) of water but offset this by drinking less of the thickened liquids. Their hydration improved over time compared with participants in the thickened liquids only group, but differences between groups were not significant. Twenty-one percent of the total sample was diagnosed with dehydration and no participants in either group were diagnosed with pneumonia. There were significantly more diagnoses of urinary tract infection in the thickened liquids only group compared to the water protocol group ($\chi^2=5.091$, $p=0.024$), but no differences between groups with regard to diagnoses of dehydration ($\chi^2=0.884$, $p=0.347$) or constipation ($\chi^2=0.117$, $p=0.733$). The findings reinforce evidence about the relative safety of water protocols for patients in rehabilitation post-stroke and provide impetus for future research into the potential benefits for hydration status and minimizing adverse health outcomes.

Key words

Drinking, deglutition, deglutition disorders, stroke, water, water-electrolyte imbalance

Introduction

Dysphagia (swallowing difficulty) is a common consequence of stroke [1]. The oral and pharyngeal phases of swallowing are commonly affected, in particular with regard to oral control of liquids and timely initiation of the pharyngeal swallow response [2,3]. Consequently, individuals with dysphagia as a result of stroke are more likely to aspirate thin liquids compared with thicker or more solid bolus consistencies [3-5]. The compensatory strategy of prescribing thickened liquids is, therefore, common practice when thin liquid aspiration is suspected [6]. The premise is that thickening a liquid makes it more cohesive and dense, reducing its flow rate. This enables many patients to better control the bolus intra-orally, thereby reducing aspiration risk before and during swallowing [7,8].

There has been growing concern, however, about the blanket prescription of thickened liquids for a number of reasons: (i) not all who aspirate thin liquids will develop pneumonia and prescription of modified diets can be unnecessarily restrictive [9,10]; (ii) patients may not like drinking thickened liquids and are, therefore, frequently non-compliant [11-13]; (iii) there is a potential for increased aspiration risk of thickened liquids post-swallow due to pharyngeal residue [14-16]; (iv) there is an increased risk of developing pneumonia or of dying if an individual aspirates thickened fluids or more solid substances as compared with thin fluids making the diagnostic process even more critical [17] and (v) there is limited empirical evidence of the medical effectiveness of fluid viscosity modification in terms of chest infection, nutritional status, hydration and mortality [14,18,19]. By far the greatest concern about thickened liquid prescription is that individuals with dysphagia do not consume enough fluids. Researchers have demonstrated that the bioavailability of water from a quantity of thickened liquids is equivalent to that from the same quantity of thin liquid [20-22] confirming that thickened liquids themselves are not the cause of dehydration. Furthermore, it is recognised that, in addition to beverages, food contributes to approximately 20% of overall fluid intake with an even greater percentage if individuals are on pureed food [23,24]. Notably, food was found to be the greatest contributor to oral fluid intake in a cohort of patients with dysphagia in acute settings [25]. However, total fluid intake has consistently been found to be inadequate for individuals with dysphagia on modified diet and liquids, especially if reliant of oral intake alone [25-29].

Patient non-compliance with thickened liquids was the primary catalyst for the development of water protocols. The Frazier Rehabilitation Centre in the USA was the first known institution to implement a 'free water protocol' [30], permitting patients to drink water between meals even though they were known to aspirate thin liquids. The premise supporting the consumption of water is that water is pH neutral and, if aspirated in small quantities, will be absorbed into the bloodstream by the alveoli and do no harm to the lungs. A retrospective chart review of 234 rehabilitation inpatients by the original authors revealed only two patients developed aspiration pneumonia after receiving the water protocol [30]. Since then, three randomized control trials have investigated the effectiveness and safety of water protocols [31-33]. These studies differed in terms of the clinical populations included, average age of participants, assessment of aspiration for participant inclusion, research design, control conditions, numbers recruited and methods of outcome measurement. Consequently, there were mixed findings about effectiveness and safety. Total fluid intake increased significantly in two of the three studies [31,32]; and there were no adverse events of pneumonia or dehydration for participants in two of the studies [31,33]. Karagiannis et al (2011) reported adverse outcomes of pneumonia for 14% of participants in the water protocol condition, particularly for patients with progressive neurological disease and poor mobility. It should be acknowledged, however, that none of the studies was powered sufficiently to conclude definitively that water protocols are safe based on the outcome of pneumonia. All three studies reported that individuals on the water protocol had increased satisfaction and quality of life. Unfortunately, adverse health outcomes related to fluid intake such as dehydration, constipation and urinary tract infection were not directly measured in any of these water protocol studies. Furthermore, none of the published data came from acute settings.

We therefore conducted the present randomized controlled trial into the effectiveness and safety of a water protocol, specifically for patients with dysphagia post-stroke. We aimed to evaluate the effects of a water protocol on hydration status and health outcomes of dehydration, pneumonia, constipation and urinary tract infection as a unique contribution to the evidence base.

Methods

The study was designed as a two-armed parallel randomized control trial (RCT) with participants randomized to receiving thickened liquids only or a water protocol. Target recruitment size was 69 participants per arm to

demonstrate a clinically meaningful difference of approximately 300ml in fluid intake between groups. Participants were recruited from the stroke units of two acute hospitals and three inpatient rehabilitation facilities in an Australian capital city. Ethics approval was granted by the human research ethics committees governing the relevant health institutions and the trial was registered with the Australian and New Zealand Clinical Trials Registry # ACTRN12610000752066. Participants were recruited between November 2009 and February 2013.

Patients were eligible for inclusion if they were over 18 years of age, an inpatient in a dedicated stroke unit, had a confirmed diagnosis of stroke (ICD-10 codes of I60, I61, I63 and I64), had a clinical dysphagia assessment indicating aspiration of thin liquid and were consuming thickened liquids. Patients were excluded if they had a known condition that may have affected swallowing pre-stroke (progressive neurological condition, brain tumour, traumatic brain injury or head or neck cancer), had a condition that put them at increased risk of respiratory complications such as chronically suppressed immune system or chronic obstructive pulmonary disease (COPD), had an acute medical illness, required supplementary non-oral feeding or fluids, had a medical order for fluid restriction or were pregnant or breast feeding. Once deemed eligible, written consent was obtained after a verbal and aphasia friendly written explanation of the research. Family members provided consent if patients were unable to due to severe aphasia, cognitive impairment or inability to comprehend English.

Demographic and stroke characteristics were recorded, including the presence or absence of stroke co-morbidities such as aphasia, apraxia, dysarthria or cognitive impairment. Mobility/ambulation was categorized as bed-bound, predominantly sitting or exerting to mobilize (either walking or self-propelling in a wheelchair). Dependence for self-care in eating, drinking and oral care was recorded along with an overall independence level as indicated by the Functional Independence Measure (FIM) [34] at admission. Weight was recorded from the nutritional screen at admission.

Clinical assessment of swallowing was conducted by the first author or by an experienced speech-language

pathologist from the facility and included an oro-motor assessment, mealtime observation with a rating of the severity of dysphagia and aspiration [35], a timed 150ml water test [36] and an oral health assessment [37]. A videofluoroscopic swallow study (VFSS) was conducted by a trained speech pathologist using a formal research protocol to confirm each participant's eligibility for the study. To be included in the study, the protocol required the patient to aspirate on two out of three thin liquid swallows and *not* aspirate on one consistency of thickened liquid and smooth pureed food. Aspiration was defined as a score of ≥ 6 on the Aspiration-Penetration scale [38]. Randomization into the two treatment arms occurred through a custom-designed website with an expectation that 138 patients would be randomized. The researcher, treating speech pathologist and patient were not blinded to the group allocation as all were involved in delivering or receiving the intervention.

In the thickened liquid only intervention, patients were allowed to drink only the mildly, moderately or extremely thickened liquid deemed safe from their VFSS. They may have consumed small amounts of water with their clinician when assessing readiness for upgrade to thin fluids. Each of the three rehabilitation facilities observed a slightly different process for providing thickened liquids (made on-site from powdered thickener or pre-packaged) but all were consistent with the Australian National Standards for fluid viscosity [39].

The water protocol used in this research was adapted from the original Frazier Water Protocol [40]. Water was permitted any time between meals but not at mealtime, with food, medication or for 30 minutes after a meal. Patients also had access to the thickened liquid that they were assessed to be safely consuming. All participants in both arms of the RCT were required to adhere to a daily oral hygiene routine which involved brushing the teeth or dentures twice daily, after breakfast and in the evening, and rinsing their mouth after lunch. This oral hygiene protocol was adapted from the South Australian Dental Service's oral health protocols for residential aged care facilities [41]. To gauge compliance with the oral hygiene protocol, purpose-made stickers were placed at the corresponding time points on each day's fluid balance chart to be signed by nursing staff as undertaken.

The primary outcome was average daily beverage intake calculated from the completion of fluid balance charts.

Only beverages were included (water, thickened cordial, coffee, tea, milo, soft-drinks, milk, flavoured milk, fruit juices), whereas fluids that began as foods such as soups, custards, ice-cream, or yoghurt were not included. Nursing staff recorded the type and amount of fluid consumed at various time points throughout a 24 hour period. Fluid balance charts were completed for every day the participant was in the intervention group until they were upgraded to thin liquid or discharged from hospital, whichever occurred first. The percentage of required fluid intake consumed was subsequently calculated for each participant whose weight had been recorded, based on a conservative standard of 30ml per kilogram of body weight [42].

A second primary outcome was hydration status as measured by biochemical analysis of blood samples taken from participants at entry to the study and at weekly intervals. The specific index used was the blood urea nitrogen/creatinine ratio (BUN/Cr). A conservative cut-off point for the ratio of greater than 20 was used to classify a participant as dehydrated, in keeping with previous studies of fluid intake and dehydration in the dysphagia population [43,44].

Development of any adverse health outcomes of particular relevance to this study, namely pneumonia, dehydration, urinary tract infection (UTI) or constipation was also recorded prospectively. These diagnoses were made by the treating medical team after clinical examination with the objective confirmation of radiographic, biochemical or pathological analysis as per standard practice.

The time to resolution of dysphagia for thin liquids was recorded by calculating the number of days from date of stroke onset to upgrade to thin liquids as determined by a qualified speech-language pathologist's assessment or following VFSS. Finally, patient satisfaction for thickened liquids and the water protocol was gauged by having participants complete a purpose designed survey of five questions at weekly intervals throughout the study. The simply phrased written questions focussed on coughing, distress, taste, thirst quenching and feel in the mouth. Participants were asked to rate these factors on a Likert scale of five pictorial responses which was designed to be accessible for cognitively and communicatively impaired participants. The highest possible score was 25; the higher the score, the greater the patient's satisfaction with the oral fluid offered. Participants in the water

protocol group were also asked whether they preferred to drink thickened liquids or water.

The Statistical Package for Social Sciences, version 22.0 was used to analyse the data [45]. Descriptive statistics were used to illustrate participants' demographics and stroke characteristics. The quantitative data of average beverage intake and BUN/Cr ratios were tested for assumptions of normality and subsequently analysed with parametric statistics. Differences between groups for fluid intake were analysed using independent samples t-tests. Repeated measures ANOVA was used to determine differences in BUN/Cr ratios across time (Day 0, Day 7, Day 14) and groups. Between group differences in adverse health outcomes were analysed using Chi-square statistics. Further analysis was undertaken to determine whether differences in average fluid intake or BUN/Cr ratios were attributable to any particular patient variables; univariate analyses were used to investigate the interaction of variables with age and sex; independent samples t-tests examined binary stroke comorbidities of presence/absence of aphasia, cognitive impairment, and dependence for drinking; one-way ANOVAs examined variables with more than two categories such as site of admission, mobility/ambulation, nature of stroke, and location of stroke; correlations determined the associations between continuous variables of age, days post stroke and FIM.

Results

Of 165 patients screened for inclusion at five hospitals, 31 patients were deemed eligible and 14 data sets were analysed (Fig 1). All completed data sets came from the sub-acute/rehabilitation sector. The demographics of the sample are summarized in Table 1. The majority of participants were male and ranged in age from 66 years to 91 years, with a mean age of 79 years. There were no significant differences in the demographic or clinical features of sex, age, days post-stroke, admission FIM, stroke comorbidities or weight at admission between participants allocated to the two groups. There were also no differences between groups at baseline on the clinical ratings of dysphagia severity, 150ml water test results, diet or fluid consistencies or oral health scores. The majority (n=11) had a moderate dysphagia for thin liquids with a moderate aspiration risk (n=9); twelve participants were consuming mildly thickened liquids and two moderately thickened liquids.

Insert Fig 1 CONSORT Flow Diagram

Insert Table 1 Demographic and Stroke Characteristics of Participants

Participants in the water protocol group consumed on average 1103ml (SD=215ml) of beverages per day, of which an average of 299ml (SD=274) was water. This total beverage intake was not significantly different to the total beverage intake of participants in the thickened liquids only group (mean=1103ml, SD=247ml) ($t_{12}=-0.002$, $p=0.998$, 95% CI = -269.641 - 269.141) (Fig 2). For the participants whose weight was recorded, those in the water protocol group consumed on average 38% of their calculated daily fluid requirements and those in the thickened liquids only group consumed 53% of their calculated daily fluid requirements ($t_5=-1.437$, $p=0.195$, 95% CI = -40.853 - 10.817). There was no significant difference in beverage intake between participants based on any of the demographic or stroke characteristics of sex, age, days post-stroke, mobility/ambulation, FIM or hospital site ($p>0.05$).

Insert Fig 2 Comparison of fluid intake of Water Protocol group and Thickened Liquids only group

Collectively, 71% of participants were classified as dehydrated at entry to the study with BUN/Cr ratio >20 . Participants in the water protocol group displayed a trend of improvement in hydration status over the two weeks: Day 0 (n= 8, mean=22.46, SD=3.70); Day 7 (n=8, mean=21.09, SD=2.47); Day 14 (n=6, mean=20.56, SD=3.70). This contrasted with results of participants in the thickened liquids only group which displayed a trend of deterioration in hydration: Day 0 (n=6, mean=20.28, SD=3.88); Day 7 (n=6, mean=21.63, SD=7.54); Day 14 (n=4, mean=24.70, SD=12.71). However, neither the independent variable of time ($F_{2,16}=0.615$, $p=0.553$, 95% CI = -5.526 - 5.705) nor the interaction of time and group ($F_{2,16}=1.475$, $p=0.258$) were statistically significant and the difference in mean BUN/Cr ratio between the two groups at each time point was also not significant (Day 0, $t_{12}=-1.070$, $p=0.306$; Day 7, $t_{12}=-0.190$, $p=0.853$ and Day 14, $t_8=-0.837$, $p=0.427$) (Fig 3). The effect size of the difference of change in hydration levels between the two groups from Day 0 to Day 7 was medium ($d=0.7$) and between Day 0 and Day 14 was large ($d=0.84$). There were no significant differences in hydration levels for participants at any time point based on any of the demographic or stroke characteristics of sex, age, days post-stroke, FIM, mobility/ambulation or hospital site ($p>0.05$).

Insert Fig 3 Changes in blood urea nitrogen/creatinine ratio between groups over time

With respect to health outcomes, 21% of the total sample was *medically* diagnosed with dehydration. There were no differences between the two groups with regard to diagnoses of dehydration ($\chi^2=0.884$, $p=0.347$) or constipation ($\chi^2=0.117$, $p=0.733$) but the thickened liquids only group had a significantly higher proportion of participants with UTI compared to the water protocol group ($\chi^2=5.091$, $p=0.024$). None of the participants in either group were diagnosed with pneumonia.

The time to resolution of dysphagia for thin liquids could only be calculated for 10 of the 14 participants; the remaining participants were discharged before their dysphagia for thin liquids resolved. The median number of days and interquartile range until resolution of dysphagia for thin liquids for the water protocol group was 27 days (IQR=20-59 days) and for the thickened liquids group was 38 days (IQR=24-42 days) ($p=0.548$).

Patient satisfaction scores for drinking thickened liquids did not differ between the groups at Day 7 ($p=0.127$) or at Day 14 ($p=0.629$). The differences in satisfaction ratings between water and thickened liquids for those in the water protocol group were also not significant at Day 7 ($p=1.0$), Day 14 ($p=0.414$) or Day 21 ($p=0.655$). Ratings for each question, such as the amount and distress of coughing experienced or the rating of taste and thirst, were similar for both groups. At Day 7, five of the eight participants in the water protocol group (63%) preferred water, at Day 14, two of four participants preferred water and at Day 21, one of two participants preferred water.

The mean oral health scores of the whole sample improved from entry to the study to Day 14. Paired samples t-test indicated a significant improvement in oral health between Day 0 and Day 7 ($t_{11}=2.569$, $p=0.026$). There was no difference in oral health scores between the water protocol and thick liquids only groups at any time point (Day 0, $t_{11}=-0.282$, $p=0.783$; Day 7, $t_{11}=1.924$, $p=0.081$; and Day 14, $t_4=1.447$, $p=0.221$).

Discussion

The purpose of this study was to determine the fluid intake and hydration status of patients with dysphagia in acute and rehabilitation facilities post-stroke and whether a water protocol resulted in improved intake and hydration. Due to recruitment difficulties, this paper presents only the findings for participants in rehabilitation facilities. The participants were representative of a typical stroke population in rehabilitation according to most demographic and stroke characteristics, although they were more dependent than stroke patients in the most recent clinical audit of Australian rehabilitation services by the National Stroke Foundation according to average FIM scores [46]. There were no significant differences in the demographic or clinical features, swallowing severity, or food or fluid consistency between patients allocated to the two arms of the RCT demonstrating that the groups were comparable at baseline and that any differences could be attributed to the intervention.

Contrary to our expectations and previous reports [31,32], the total beverage intake of participants in the water protocol group of 1103ml was no higher than for those who consumed thickened liquids only, demonstrating that participants offset the amount of water they consumed by drinking less of the thickened liquids. Given there was no other influence on fluid intake from demographic or stroke related clinical factors such as age, sex, mobility/ambulation or level of dependency, it is likely that the dysphagia itself limited their intake. Even when given the choice to drink water, participants in the water protocol group drank more thickened liquids (807mls) than water (299mls), a finding that is consistent with the other published water protocol studies [31-33].

Of concern was that a large number of participants (71%) were classified as dehydrated at entry to the study as objectively measured by BUN/Cr ratio. Notably, the hydration of participants in the water protocol group demonstrated a trend of improvement, in contrast to the deteriorating trend of those in the thickened liquids only group. Although none of these changes over time were significant, the calculated effect sizes were promising. As there were no differences in hydration measures between the groups according to factors such as age, sex, mobility/ambulation, or dependency, the finding suggests that water may have contributed to the apparent difference in trajectories, despite participants in the water protocol group drinking only 300ml of water on average per day. The exact mechanism for this apparent difference in hydration, without an associated overall

increase in fluid intake, from a physiological and biochemical point of view, is not known. The groups were equivalent in terms of baseline diet consistencies, so it cannot be assumed that food contributed to the difference. Rather, it could be hypothesized that water is more accessible to the body than thickened liquids for the purposes of hydration, particularly in removing waste products from the blood, a finding that is juxtaposed to research which indicated there is no evidence for the reduced availability of water from thickened liquids [22]. Further biochemical exploration of the potential benefits to hydration of consuming small amounts of water in the rehabilitation phase of dysphagia post-stroke is warranted.

This study provided unique findings about health outcomes. Participants in the thickened liquids only group had significantly more UTIs than those in the water protocol group. It is recognised that UTIs can be associated with many factors other than fluid intake, such as incontinence, catheterisation, medications and mobility but, in theory, these other factors should have been accounted for by the randomization process. In this study, 21% of participants across both groups were medically diagnosed to be dehydrated. This is in contrast to the findings of other studies of water protocols, which found no adverse events for any of their participants [31,33]. This discrepancy may be attributable to the differing definitions for dehydration and follow-up periods. Notably, no participants in either group developed aspiration pneumonia, a finding consistent with previous reports [31,33] but in contrast to another [32]. The mandated oral hygiene routine which resulted in significant improvement in participants' oral health scores in just one week from enrolment may have contributed to this outcome.

The resolution of dysphagia for thin liquids for participants in the water protocol group was faster, albeit not significantly, than for those in the thickened liquids only group, in line with a previous report [33]. Together, these findings may indicate that allowing patients to “practice” drinking thin liquids in the relatively safe form of water, may in fact promote recovery of dysphagia for thin liquids, in accordance with the principles of experience dependent neuroplasticity [47,48].

A surprising finding was that participants in the water protocol group rated their overall satisfaction with water at a similar level to that for thickened liquids and, when asked their preferred drink, were evenly split in their

choice between water and thickened liquids. On average, they rated the taste of thickened liquids higher than the taste of water. It would appear that individuals' taste preferences play an important role in what they drink when given a choice; some like the taste of tap water, others don't. The participants' ambivalence about thickened liquids is in contrast to the common perception of clinicians, who frequently report that patients' dislike of thickened liquids is the main reason for their poor intake [12,49], and previously published satisfaction reports about water protocols [31-33].

It is acknowledged that this study had methodological limitations and the findings should therefore be interpreted in this context. The use of fluid balance charts as a measure of fluid intake may have resulted in inaccurate amounts being recorded despite procedures being established to minimize errors. The amount of beverages offered to individual participants in this study was not controlled or recorded and may have varied between individuals and institutions which may have differentially influenced consumption. In addition, fluid from food sources was not measured although it was assumed that the randomization process and equivalence of groups at baseline accounted for any differences in fluid intake from food. Furthermore, it is acknowledged that the use of a single biochemical metric (BUN/Cr ratio) is a limitation as the clinical diagnosis of dehydration is complex and highly variable in any clinical setting. Clearly, sample size was a major limitation and, despite being designed as a multi-centre RCT, the number of patients proceeding to group allocation and intervention was small. This resulted in the study being underpowered to demonstrate hypothesized differences between groups. Reasons for poor recruitment included: the narrow window of time between the patient with dysphagia no longer requiring supplementary non-oral feeding and then being upgraded to thin liquids due to the rapid recovery in the first weeks post-stroke [50]; the large numbers of exclusions due to COPD; and the number of potential candidates who were deemed to be aspirating thin liquids on a clinical assessment but subsequently had to be excluded as aspiration of thin liquid was not detected during VFSS. Notably, the sample size of the present study was similar to previous studies utilising similar exclusion criteria and instrumental assessment to classify participants as aspirating [31,33]. Whilst distinct exclusion and inclusion criteria are necessary for experimental rigour, it is acknowledged that generalizability to the wider stroke population is thereby sacrificed. Future studies of water protocols may benefit from a thorough interdisciplinary review of inclusion and exclusion criteria, in particular with regard to participants' respiratory status.

In conclusion, the water protocol employed in this study did not result in an increase in total fluid intake. However, those who were permitted water had an improving trajectory of hydration levels compared to those on thickened liquids only, suggesting even a small amount of water per day may make a difference to hydration levels. There is also an indication that water protocols may hasten the resolution of dysphagia for thin liquids. Given there were no increased adverse outcomes for participants who were allowed water and, importantly, there were no diagnoses of pneumonia, the findings reinforce current evidence about the relative safety of water protocols for patients in rehabilitation post-stroke with similar profiles (i.e. no history of COPD, reduced immune status, neuro-degenerative disease or head and neck cancer). Future research should revisit the exclusion criteria to widen potential applicability to more patients post-stroke, consider the measurement of total fluid intake by including fluid from food sources, use multiple indices to measure hydration and investigate the safety of water protocols for patients in acute settings.

Table 1 Demographic and Stroke Characteristics of Participants

		Total sample n (%)	Water Protocol n	Thick only n	p value
	Participants	14 (100)	8	6	
Sex	Male	10 (71)	6	4	0.733
Age	Mean in years (SD)	79 (6.4)	78 (6.8)	80 (6.4)	0.691
Stroke type	Infarct	13 (93)	7	6	0.369
	Intracerebral haemorrhage	1 (7)	1	0	
Stroke Location	Cortical	7 (50)	3	4	0.233
	Sub-cortical	4 (29)	2	2	
	Brainstem	3 (21)	3	0	
	Cerebellar	0 (0)	0	0	
Stroke Lateralisation	Left	10 (71)	7	3	0.124
	Right	4 (29)	1	3	
	Bilateral	0 (0)	0	0	
Time post stroke	Mean no. days (SD)	19 (8)	19.1 (8.4)	19.7 (9.3)	0.911
FIM	Mean (SD)	59 (19)	57 (6.4)	60 (22.4)	0.864
Weight	Mean (SD)	78.7 (19.6)	99 (1.4)	70.6 (17)	0.075

Stroke	Aphasia	3 (21)	1	2	
comorbidities	Cognitive impairment	5 (36)	3	2	
	Not exerting to mobilize	9 (64)	5	4	
	Motor or ideational apraxia	1 (7)	0	1	
	Dysarthria	12 (86)	7	5	
	Apraxia of speech	2 (14)	0	2	
	Dependence for oral care	4 (29)	1	3	
	Dependence for pouring drinks	2 (14)	0	2	
	Dependence for drinking from a cup	0 (0)	0	0	
	Oral health	Mean score /16 (SD)	4.85 (3.44)	4.63 (2.50)	5.20 (4.92)
Diet consistency	Smooth pureed	1 (7)	0	1	
	Minced and moist	7 (50)	4	3	
	Soft	6 (43)	4	2	
Liquid consistency	Mildly thick (nectar)	12	6	6	
	Moderately thick (honey)	2	2	0	

CONSORT Flow Diagram

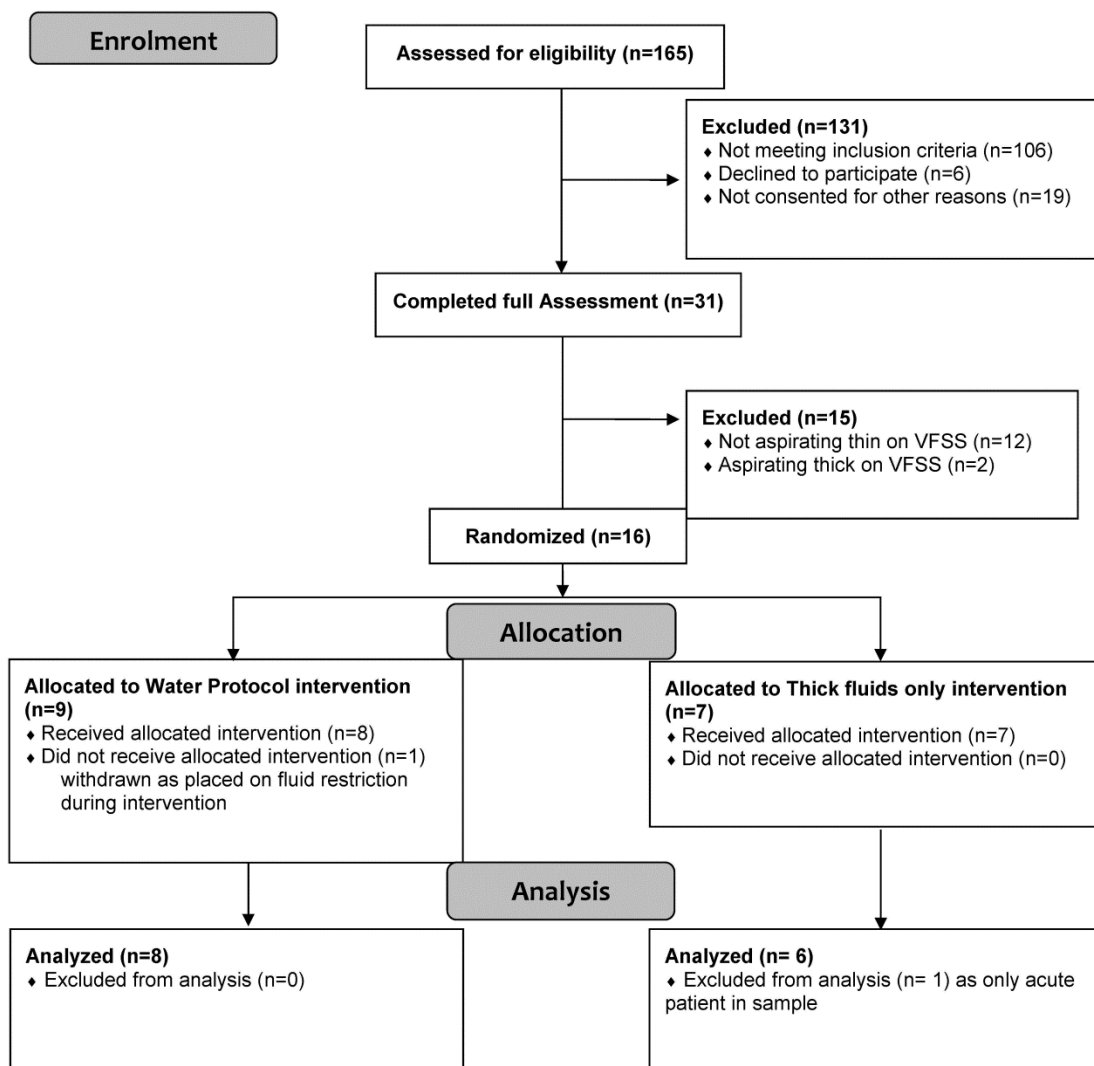


Fig 1 CONSORT Flow Diagram

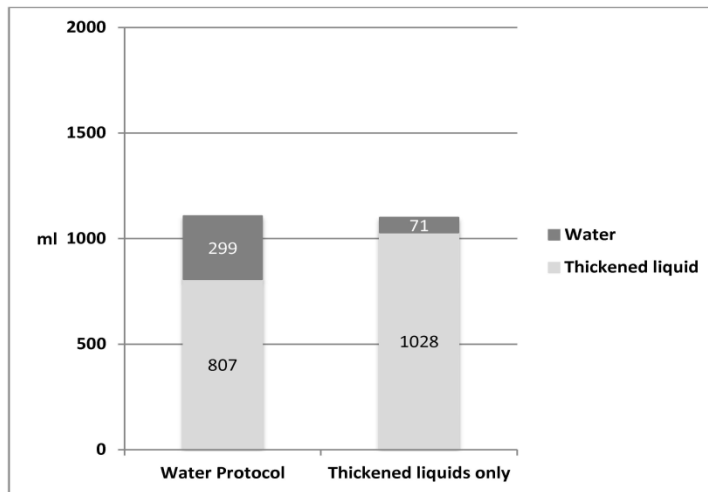


Fig 2 Comparison of fluid intake of Water Protocol group and Thickened Liquids only group

Participants in the water protocol group consumed 1103ml on average per day, of which 299ml was water. This was not significantly different to the average daily consumption (1103ml) of participants in the thickened liquids only group.

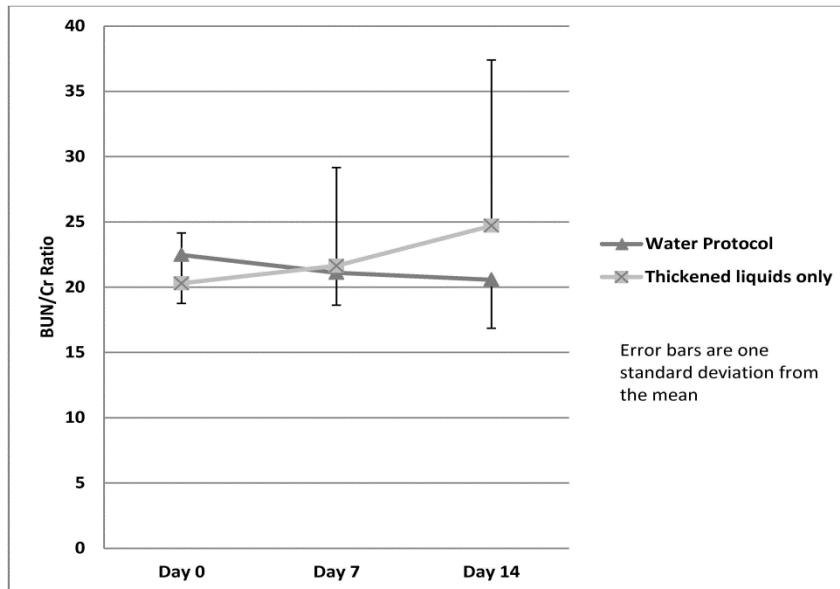


Fig 3 Changes in blood urea nitrogen/creatinine ratio between groups over time

A higher BUN/Cr ratio represents poorer hydration. Participants in the water protocol group had a trend of improving hydration and those in the thickened liquids only group displayed a trend of deterioration in hydration but none of the differences between groups at the three time points were significant.

References

1. Martino R, Foley NC, Bhogal S, Diamant N, Speechley M, Teasell R (2005) Dysphagia after stroke: Incidence, diagnosis, and pulmonary complications. *Stroke* 36:2756-2763
2. Mann G, Hankey GJ, Cameron D (1999) Swallowing function after stroke: Prognosis and prognostic factors at 6 months. *Stroke* 30 (4):744-748
3. Logemann JA (1998) Evaluation and treatment of swallowing disorders. 2nd edn. ProEd, Austin, TX
4. Bulow M, Olsson R, Ekberg O (2003) Videoradiographic analysis of how carbonated thin liquids and thickened liquids affect the physiology of swallowing in subjects with aspiration on thin liquids. *Acta Radiologica* 44:366-372
5. Kuhlemeier KV, Palmer JB, Rosenberg D (2001) Effect of liquid bolus consistency and delivery method on aspiration and pharyngeal retention in dysphagia patients. *Dysphagia* 16:119-122
6. Mertz Garcia J, Chambers E, Molander M (2005) Thickened liquids: Practice patterns of speech-language pathologists. *American Journal of Speech-Language Pathology* 14:4-13
7. Huckabee M, Pelletier C (1999) Management of adult neurogenic dysphagia. Singular, San Diego, CA
8. Hamlet S, Choi J, Zormeier M, Shamsa F, Stachler R, Muz J (1996) Normal adults swallowing of liquid and viscous material: Scintigraphic data on bolus transit and oropharyngeal residues. *Dysphagia* 11:41-47
9. Langmore SE, Terpenning MS, Schork A, Chen Y, Murray J, Lopatin D, Loesche W (1998) Predictors of aspiration pneumonia: How important is dysphagia? *Dysphagia* 13:69-81
10. Marik PE (2001) Aspiration pneumonitis and aspiration pneumonia. *The New England Journal of Medicine* 344 (9):665-671
11. Colodny N (2005) Dysphagic independent feeders' justifications for noncompliance with recommendations by a speech-language pathologist. *American Journal of Speech-Language Pathology* 14 (1):61-70
12. Mertz-Garcia J, Chambers E, Molander M (2005) Thickened liquids: Practice patterns of speech-language pathologists. *American Journal of Speech - Language Pathology* 14 (1):4-13
13. King J, Ligman K (2011) Patient noncompliance with swallowing recommendations: Reports from speech-language pathologists. *Contemporary Issues in Communication Science and Disorders* 38:53-60
14. Clavé P, De Kraa M, Arreola V, Girvent M, Farre R, Palomera E, Serra-Prat M (2006) The effect of bolus viscosity on swallowing function in neurogenic dysphagia. *Alimentary pharmacology & therapeutics* 24 (9):1385-1394

15. Steele CM, Huckabee M (2007) The influence of orolingual pressure on the timing of pharyngeal pressure events. *Dysphagia* 22 (1):30-36
16. Steele CM, Alsanei WA, Ayanikalath S, Barbon CEA, Chen J, Cichero JAY, Coutts K, Dantas RO, Duivestein J, Giosa L (2014) The influence of food texture and liquid consistency modification on swallowing physiology and function: A systematic review. *Dysphagia* 30 (1):2-26
17. Schmidt J, Holas M, Halvorson K, Reding M (1994) Videofluoroscopic evidence of aspiration predicts pneumonia and death but not dehydration following stroke. *Dysphagia* 9 (1):7-11
18. Goulding R, Bakheit A (2000) Evaluation of the benefits of monitoring fluid thickness in the dietary management of dysphagic stroke patients. *Clinical Rehabilitation* 14:119-124
19. Foley N, Teasell R, Salter K, Kruger E, Martino R (2008) Dysphagia treatment post stroke: a systematic review of randomised controlled trials. *Age and Ageing* 37 (3):258-264
20. Cichero JAY (2013) Thickening agents used for dysphagia management: Effect on bioavailability of water, medication and feelings of satiety. *Nutrition Journal* 12 (54)
21. Hill RJ, Dodrill P, Bluck LJ, Davies PS (2010) A novel stable isotope approach for determining the impact of thickening agents on water absorption. *Dysphagia* 25 (1):1-5
22. Sharpe K, Ward L, Cichero JAY, Sopade P, Halley P (2007) Thickened fluids and water absorption in rats and humans. *Dysphagia* 22:193-203
23. Institute of Medicine of the National Academies (2004) Dietary reference intakes for water, potassium, sodium, chloride, and sulfate. National Academies Press, Washington, DC
24. National Health and Medical Research Council (2003) Dietary guidelines for Australian adults. A guide to healthy eating. Commonwealth of Australia, Canberra, ACT
25. Vivanti AP, Campbell KL, Suter MS, Hannan-Jones MT, Hulcombe JA (2009) Contribution of thickened drinks, food and enteral and parenteral fluids to fluid intake in hospitalised patients with dysphagia. *Journal of Human Nutrition and Dietetics* 22 (2):148-155
26. Whelan K (2001) Inadequate fluid intakes in dysphagic acute stroke. *Clinical Nutrition* 20 (5):423-428
27. Patch CS, Mason S, Curcio-Borg F, Tapsell LC (2003) Thickened fluids: Factors affecting wastage. *Advances in Speech-Language Pathology* 5:73-77
28. Murray J, Miller M, Doeltgen S, Scholten I (2014) Intake of thickened liquids by hospitalized adults with dysphagia after stroke. *International Journal of Speech-Language Pathology* 16 (5):486-494
29. Finestone HM, Foley NC, Woodbury MG, Greene-Finestone L (2001) Quantifying fluid intake in dysphagic

- stroke patients: A preliminary comparison of oral and non-oral strategies. *Archives of Physical Medicine and Rehabilitation* 82:1744-1746
30. Panther K (2005) The Frazier free water protocol. *Perspectives on Swallowing and Swallowing Disorders (Dysphagia)* 14 (1):4-9
31. Carlaw C, Finlayson H, Beggs K, Visser T, Marcoux C, Coney D, Steele CM (2012) Outcomes of a pilot water protocol project in a rehabilitation setting. *Dysphagia* 27:297–306
32. Karagiannis M, Chivers L, Karagiannis T (2011) Effects of oral intake of water in patients with oropharyngeal dysphagia. *BMC Geriatrics* 11 (9)
33. Garon BR, Engle M, Ormiston C (1997) A randomized control study to determine the effects of unlimited oral intake of water in patients with identified aspiration. *Journal of Neurological Rehabilitation* 11:139-148
34. State University of New York at Buffalo (1993) Guide for the Uniform Data Set for Medical Rehabilitation (Adult FIM). version 4.0 edn., Buffalo, NY
35. Perry A, Skeat J (2004) *AusTOMs for Speech Pathology*. La Trobe University, Melbourne, Vic. doi: ISBN 1-920948-54-6
36. Hughes TAT, Wiles CM (1996) Clinical measurement of swallowing in health and in neurogenic dysphagia. *Quarterly Journal of Medicine* 89:109-116
37. Chalmers JM, King PL, Spencer AJ, Wright FA, Carter KD (2005) The Oral Health Assessment Tool - validity and reliability. *Australian Dental Journal* 50:191-199
38. Rosenbek J, Robbins J, Roecker E, Coyle J, Wood J (1996) A penetration-aspiration scale. *Dysphagia* 11 (2):93-98
39. Atherton M, Bellis-Smith N, Cichero J, Suter M (2007) Texture-modified foods and thickened fluids as used for individuals with dysphagia: Australian standardised labels and definitions. *Nutrition and Dietetics* 64 (2 Supp.):s53-s76
40. Panther K (2003) The Frazier Rehab Institute Water Protocol. <http://www.kentuckyonehealth.org/frazier-water-protocol>. Accessed 29 January 2014
41. South Australian Dental Service (2004) Oral health protocols for residential aged care facilities. <http://www.sadental.sa.gov.au/>.
42. Chidester JC, Spangler AA (1997) Fluid intake in the institutionalized elderly. *Journal of American Dietetic Association* 97 (1):23-30
43. Rowat A, Graham C, Dennis M (2012) Dehydration in hospital-admitted stroke patients: Detection,

frequency, and association. *Stroke* 43 (3):857-859

44. Leibovitz A, Baumoehl Y, Lubart E, Yaina A, Platinovitz N, Segal R (2007) Dehydration among long-term care elderly patients with oropharyngeal dysphagia. *Gerontology* 53 (4):179-183

45. IBM Corp. (2013) IBM SPSS Statistics for Windows, Version 22.0. IBM Corp., Armonk, NY

46. National Stroke Foundation (2010) National Stroke Audit Rehabilitation Services 2010. Melbourne, Victoria

47. Kleim JA, Jones TA (2008) Principles of experience-dependent neuroplasticity: Implications for rehabilitation after brain damage. *Journal of Speech, Language and Hearing Research* 51:S225

48. Robbins J, Butler S, Daniels SK, Gross R, Langmore SE, Lazarus CL, Martin-Harris B, McCabe D, Musson N, Rosenbek JC (2008) Swallowing and dysphagia rehabilitation: translating principles of neural plasticity into clinically oriented evidence. *Journal of Speech, Language, and Hearing Research* 51 (1):S276-S300

49. Murray J, Doeltgen S, Miller M, Scholten I (2014) A survey of thickened fluid prescribing and monitoring practices of Australian health professionals. *Journal of Evaluation in Clinical Practice* 20 (5):596-600

50. Smithard DG, O'Neill PA, England RE, Park CL, Wyatt R, Martin DF, Morris J (1997) The natural history of dysphagia following a stroke. *Dysphagia* 12 (4):188-193

Corresponding author contact details:

Jo Murray, Speech Pathology and Audiology, School of Health Sciences, Flinders University, GPO Box 2100, Adelaide SA 5001 AUSTRALIA

Email: joanne.murray@flinders.edu.au

Conflict of Interest: None declared

Sources of Funding:

This research was supported by the Royal Adelaide Hospital/Institute of Medical and Veterinary Science Clinical Research Grant for Allied Health, Nursing and Pharmacy [January 2009] and a Clinical Research Development Grant awarded to the first author by the National Stroke Foundation, Australia [dated 15th December 2011]

Acknowledgements

The authors gratefully acknowledge the staff of the participating rehabilitation centres for their invaluable assistance during the data collection process.