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A Randomized Clinical Trial of an Intervention to Relieve Thirst and Dry Mouth in Intensive Care Unit Patients

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Abstract

Purpose—To test an intervention bundle for thirst intensity, thirst distress, and dry mouth, which are among the most pervasive, intense, distressful, unrecognized, and under-treated symptoms in ICU patients, but for which data-based interventions are lacking.

Methods—Single-blinded, randomized clinical trial in three ICUs in a tertiary medical center in urban California. 252 cognitively intact patients reporting thirst intensity (TI) and/or thirst distress (TD) scores 3 on 0–10 numeric rating scales (NRS) were randomized to Intervention or Usual Care groups. A Research Team Nurse (RTN#1) obtained patients' pre-procedure TI and TD scores and reports of dry mouth. She then administered a thirst bundle to the Intervention group: oral swab wipes, sterile ice cold water sprays, and a lip moisturizer, or observed patients in the Usual Care group. RTN#2, blinded to group assignment, obtained post-procedure TI and TD scores. Up to 6 sessions per patient were conducted across two days.

Results—Multilevel linear regression determined that the average decreases in TI and TD scores from pre-procedure to post-procedure were significantly greater in the Intervention group (2.3 and 1.8 NRS points, respectively) versus the Usual Care group (0.6 and 0.4 points, respectively) ($p <$

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0.05). The Usual Care group was 1.9 times more likely than the Intervention group to report dry mouth for each additional session on Day 1.

Conclusion—This simple, inexpensive thirst bundle significantly decreased ICU patients' thirst and dry mouth and can be considered a practice intervention for patients experiencing thirst.

Clinical trial registered with www.clinicalTrials.gov (NCT01015755).

Keywords

thirst relief; dry mouth; ICU; symptom; non-pharmacological; palliation

INTRODUCTION

Thirst is a perception that provokes the urge to drink fluids. [1] It is a multidimensional symptom that is described in terms of intensity and distress and is sometimes associated with dry mouth, [2] termed xerostomia. [3] Thirst is poorly recognized in intensive care unit (ICU) practice. [4, 5] Yet, research has identified it as one of the most pervasive, intense, and under-treated symptoms in ICU patients. [6, 7] Over 70% of ICU cancer patients reported unsatisfied thirst at the highest levels of intensity, [8] and almost all chronically, critically ill patients in a hospital-based Respiratory Care Unit reported moderate or severe thirst. [9] Of 405 symptom assessments completed by 171 ICU patients, thirst was reported in 70% of patient assessments, and it was rated as more intense than fatigue, anxiety, restlessness, hunger, dyspnea, pain, sadness, fear, and confusion. [10] The rationale for developing and testing an effective thirst relief intervention is provided by the basic compassionate care tenet that ICU patients' symptoms should be palliated. [11]

No previous study of ICU patients provides empirical guidance on thirst relief during critical illness. [6] Protocols for mouth care in ICU patients, [12, 13] including those for ventilator-associated pneumonia (VAP) prevention, [14] have eliminated the use of lemon-glycerin swabs because they produce an acid pH, [15] dry oral tissues, [16] cause irreversible softening and erosion of tooth enamel, [17] exhaust salivary mechanisms, and worsen xerostomia. [18] Artificial saliva substitutes are ineffective for relieving dry mouth. [19] There is no research basis for ice chips being effective for relief of thirst or dry mouth, and ice chips are contraindicated for many critically ill patients.

Prior research evaluating individual topical measures to relieve thirst or dry mouth in healthy subjects or non-ICU patients suggested the effectiveness of sprays of cold sterile water from squirt bottles, [20–22] swabs of cold sterile water, [23–26] and a menthol moisturizer. [21, 27] Cold water satiates thirst more effectively than body temperature water [28] and is preferred because it offers greater relief from mouth dryness. [24, 29] Cold water also may stimulate greater saliva production than warmer water, [21] [25] which may, in turn, alleviate mouth dryness. [25] Sprays of water from plastic squirt bottles and swabs to moisten the mouth and tongue have been previously shown to be effective for heart failure patients experiencing thirst from fluid restriction. [22] Like cold water, menthol stimulates sensory cold receptors in the mouth by increasing nerve discharge from cold receptors. [27] In the present study, we tested whether combining these measures as an “intervention

bundle,” focusing specifically on ICU patients, would effectively reduce thirst intensity (TI) and thirst distress (TD). (Study results were previously published in abstract form.) [30, 31] The comparison group received usual care, i.e., the day-to-day care (i.e., monitoring and management) provided by patients’ clinicians as part of usual practice.

Two hypotheses were tested:

- Hypothesis 1** Thirst intensity and thirst distress will decrease significantly more from pre-procedure to post-procedure in ICU patients who receive a thirst Intervention compared to those who receive Usual Care.
- Hypothesis 2** Dry mouth will decrease significantly in ICU patients who receive a thirst Intervention bundle compared to those who receive Usual Care.

MATERIALS and METHODS

Site and Sample

This study was conducted as a single-blinded, longitudinal, randomized clinical trial. We tested the intervention in each patient for up to six times to determine the effect at each of several time periods. We report our findings guided by Consolidated Standards Of Reporting Trials (CONSORT) statement for randomized trials of nonpharmacological treatment. [32] Patients were recruited from medical-surgical, neurological, and cardiovascular ICUs in a tertiary medical center in urban California (77 adult beds.) Although each ICU serves different populations, they follow uniform practice standards. Inclusion criteria were: age ≥ 18 years; ICU stay ≥ 24 hours; English proficient; oriented to name, date of birth, and location; a Richmond Agitation Sedation Scale (RASS) [33] score of -1 to $+1$ (i.e., not sedated or agitated); and either a TI or TD score of ≥ 3 on a $0 - 10$ numeric rating scale (NRS), which was assessed at the time of screening. Exclusion criteria were open sores or desquamation on the mouth or lips, a history of dementia, or a medical condition that contraindicated the intervention (e.g., oral surgery). Since thirst could occur in patients unrelated to nil per os (NPO) status, patients were enrolled in the study regardless of whether they were allowed fluids by mouth. All research team members were trained extensively on the procedures and systematically observed for protocol compliance.

Pre-screening for Thirst

A research team nurse (RTN) used NRSs (0 to 10) to obtain patient thirst ratings at baseline and during subsequent assessments. The NRS has been widely used to assess pain intensity and other symptoms; has face, construct, and concurrent validity; [34] and is feasible for use in ICUs. To measure TI, the RTN asked the patient, “how intense is your thirst, on this scale, where 0 = no thirst and 10 = worst possible thirst?” To measure TD, the RTN asked, “how distressing [or bothersome] is your thirst, on this scale, where 0 = no distress and 10 = very distressing?” For patients unable to communicate orally due to endotracheal intubation, the RTN held up a laminated sheet showing the NRS and/or asked the patient to nod affirmatively when she pointed to the number that corresponded to their TI or TD. Independent scoring by two RTNs for 50 assessments was initially compared to assure inter-rater reliability. Patients who met eligibility criteria were invited to participate in the study.

Approval was obtained from the Institutional Review Board at the study institution, and informed consent was obtained for all participants, either directly or through an appropriate surrogate.

Study Protocol

Patients received either the Intervention or Usual Care according to randomization by the RTN enrolling the patient (RTN#1) by a code drawn from an envelope. The study procedure occurred during three 15-minute sessions per day for two days, conducted between 10 AM and 6 PM up to seven days per week. There was a minimum of 30 minutes between each of the 3 sessions; the maximum time between sessions varied as a factor of other patient care activities. RTN#1 and a second RTN who was blinded to group assignment, RTN#2, worked together to implement the study procedure.

The detailed study protocol is in Supplemental Table 1. In brief, pre-procedure TI and TD scores were obtained at the beginning of each session, and patients were asked whether their mouth felt dry. Assessment was done to determine if the patient had stickiness or dryness in the mouth or around lips; had split skin at the corners of the mouth; or cracked lips. Intervention group patients then received the thirst bundle: oral swabs and water sprays, and menthol moisturizer applied to the patient's lips. The full intervention was delivered in 15 minutes. Patients in the Usual Care group were observed for a 15 minute period. RTN#1 did not interfere with the patients' normal nursing activities. Immediately after each 15 minute session, RTN#2, blinded to the patient's pre-procedure thirst scores and group allocation (intervention materials were removed from the room), was called to the patient's bedside by RTN#1. RTN#2 obtained the patients' post-procedure TI and TD scores. After a minimum of 30 minutes, this procedure was repeated twice on Day 1 and up to three sessions on Day 2, if the patient remained in ICU. Patient participation ended when they were transferred from the unit or when 2 RTNs were not available on Day 2. All enrolled patients contributed data to the analyses. Data collection began in April 2010 and ended in June 2012.

Demographic and clinical characteristics of patients such as age, gender, laboratory values, medications, and first 24 hour APACHE II score [35] were abstracted from the medical record on the study day. Safety monitoring of the intervention was performed to ensure that the intervention had no adverse effect on patients. An interim analysis showed no increase in thirst, so the study protocol was continued.

Statistical Analyses

Statistical results are expressed as numerical values and percentages for categorical variables and as means, standard deviations (SD), medians, and 1st and 3rd quartiles [Q1;Q3] for continuous variables. Comparisons were based on the χ^2 test for categorical data and on the t-test for continuous data. Multilevel linear regression with random intercepts was used to test hypothesis 1, that TI and TD will decrease significantly more from pre-procedure to post-procedure in ICU patients who receive a thirst Intervention compared to those who receive Usual Care. [36, 37] This approach, unlike ANOVA, allows for missing data on the dependent variable (i.e., when patients did not complete all 6 sessions) as well as unbiased estimates of both fixed and random effects. Multilevel linear regression is also an

appropriate analytical method when observations are non-independent. In a two-level linear mixed models design (multilevel regression model), repeated measures are at level one, and individuals (“clusters”) are at level two.

Group assignment (Intervention or Usual Care) was the between subjects factor. Our hypothesis 1 tested the difference between groups in average TI and TD scores from pre- to post-procedure. However, in preliminary analyses of the full factorial model, we tested three within subjects factors: (1) the difference between groups for the pre- to post-procedure TI and TD scores, (2) the difference between groups due to session order, and (3) and the difference between groups for day one compared to day two. The “sessions” and “days” factors were of secondary interest but were examined to determine whether the pre- to post-procedure effect of the intervention was influenced by multiple interventions (i.e., 3 per day), and/or whether the effect of the intervention differed if it was given on two sequential days. Supplementary Table 2 provides a detailed explanation of statistical methods used in this study as well as their rationale. A power analysis determined that at least 69 patients should remain in each group at the end of the treatment period, for a total of 138. Anticipating attrition due to patient transfers and other clinical reasons, we chose to enroll 252.

For hypothesis 2, multilevel logistic regression was used to determine if there was a change in the odds that patients would experience dry mouth across sessions and, if so, whether the change differed according to the presence of the thirst intervention. This analysis focused on Day 1 because there were more assessments on Day 1 than Day 2. The difference between groups in dry mouth was analyzed by multilevel logistic regression using Stata/SE for Windows® Release 12 because of the superiority of this estimation method compared to the SPSS method.

Additional statistical analyses (Chi Square, t-tests, and multilevel logistic regression) were performed post hoc to further explore the meaning of results. Specifically, differences between groups were analyzed for fluid consumption, NPO orders, oral care practices, and the specific ICU (medical-surgical, neurovascular, cardiovascular) in which patients were located. All data were de-identified and double entered into IBM Statistical Package for the Social Sciences (SPSS) for Windows® version 20 (Armonk, NY, 2011).

RESULTS

A total of 1417 patients were screened for TI and TD, 950 patients met eligibility criteria, and 252 provided informed consent (See Figure 1 for CONSORT diagram). Patients were randomized to the Intervention group (n=127) and the Usual Care group (n=125). There were few statistically significant differences in demographic, clinical, and biological characteristics between the two groups (Table 1).

Results from the preliminary analysis of the full factorial MLR model showed that the potentially confounding influences of session order and day were not significant; i.e., they did not influence the individual differences between the Intervention and the Usual Care groups’ thirst scores from pre-procedure to post-procedure (the between subjects effect.)

Therefore, for parsimony, these non-significant effects were removed, and the model was re-run in order to focus on hypothesis 1, i.e., the mean change in pre-to-post procedure thirst scores for the two groups. Decreases in pre- to post-procedure TI and TD scores were significantly greater in the Intervention group than in the Usual Care group ($p < 0.001$), in both the full factorial model and in the more parsimonious model, from which the results are reported. Specifically, TI scores in the Intervention group decreased 2.3 points, on average, while scores in the Usual Care group decreased 0.6 points, on average. TD scores in the Intervention group decreased 1.8 points, on average, while scores in the Usual Care group decreased 0.4 points, on average. Differences in TI and TD, based on the multilevel regression analyses, are shown in Table 2. Table 3 shows the pre- and post-procedure mean thirst scores in both groups across the two days, and Supplemental Figures 2 and 3 show scores at each session.

Patients were able to differentiate thirst from dry mouth. Table 4 presents the odds of patients in the Intervention and Usual Care groups reporting dry mouth across sessions. Multilevel logistic regression showed that the Usual Care group was 1.9 times more likely to report dry mouth compared to the Intervention Group for each additional assessment ($p < 0.04$).

No group differences were found regarding oral care practices and ICU assignment. Nor was there a significant difference between groups in total amount of fluids received during the 24 hour period (Table 1). However, significantly more patients in the Intervention group had an NPO order (35% versus 22%, respectively, $p = 0.02$). Furthermore, significantly fewer patients in the Intervention group received oral fluids during the 24 hour period and study sessions (65% versus 77%, respectively, $p = 0.03$).

DISCUSSION

Amelioration of thirst has not previously been a research focus in ICU patients despite documentation that thirst is a prevalent and intense symptom. In this study, we tested a safe, simple, and inexpensive 3-part intervention bundle for ICU patients experiencing thirst. Measured on 0–10 NRS, the intervention decreased TI by 2.3 points and TD by 1.8 points from pre- to post-procedure regardless of the number of sessions or days in which patients participated. That is, the intervention was effective at each of the 6 sessions. While not previously examined in thirst research, this degree of difference exceeds the “minimally clinically significant” criterion of 1.7 points on an NRS determined in pain research. [38] Thus, these decreases in thirst can be considered both statistically and clinically significant. Furthermore, using criteria developed for pain responses, [39] TI and TD scores decreased from “moderate” (NRS scores from 5 – 6) to “minimal” levels (i.e., NRS scores from 1 – 4).

Lower TI and TD scores occurred in the Intervention group in spite of the fact fewer received oral fluids; however, the total amount of fluids received in a 24 hour period was not significantly different between groups. Also, more thirst Intervention patients had a decrease in dry mouth than Usual Care patients.

The 3-part thirst intervention was developed from individual, research-based treatments found to be effective in healthy subjects or patients outside of ICUs. To our knowledge, these treatments had not been tested in ICU patients or evaluated as a bundle, either in ICU patients or any other patient group. Data from the present study showed that combining the individual thirst treatments in our bundled intervention helped relieve thirst and dry mouth, which cause distress for many ICU patients.

The positive effect of the intervention that we tested is consistent with physiologic data showing that thirst relief is independent of swallowing and gastric distention but, rather, appears to be mediated by inhibition of vasopressin secretion through cold sensitive oropharyngeal receptors. [23] This process of thirst relief has been termed “preabsorptive satiety” [21]^{p.30} or inhibition of thirst by actions in the oropharynx itself. [24] While oropharyngeal stimulation/satiety from sprays of cold water may help explain the reduction in thirst found in Intervention patients, symptom relief through oropharyngeal stimulation was not independently investigated. Still, this thirst intervention, which does not require swallowing fluids that reach the stomach, seems suitable for many ICU patients who are not permitted to or unable to swallow oral fluids. Preabsorptive satiety may also be influenced by menthol due to the menthol’s cooling sensation, and the peppermint odor of menthol may be perceived as pleasant. [21]

This study has limitations. Our recruitment rate was modest, perhaps due to the patients’ extreme tiredness or stress caused by their illness and/or multiple ICU events. However, a heterogeneous sample of over 250 patients was enrolled. Second, the proportion of mechanically ventilated (MV) patients was small, primarily due to sedation levels which limited patient ability to report thirst scores. Yet, MV patients, whose mouths are open and who are not usually allowed to drink or take ice chips, are often thirsty [8] and might benefit from our intervention. Future research is required with MV patients who are cognitively clear enough to self-report to demonstrate benefit to them and extend generalizability of results.

Some patients received small amounts of fluids during the procedure. However, since more Usual Care patients received fluids, the intervention effect might actually be underestimated. Thus, thirst relief measures can be given to patients regardless of their oral fluid status. Additionally, the effectiveness of the individual parts of the thirst bundle was not analyzed, so we do not know if thirst reduction requires all parts of the bundle. Finally, since there were at least 30 minutes between each session, we do not know the precise duration of effectiveness of the thirst bundle. In actual practice, versus research conditions, the thirst bundle could be used more frequently, as needed. The necessary materials (i.e., ice cold water in spray bottles, swabs and moisturizer) could be at the patient’s bedside. Either the patient’s nurse or a family member could use the materials to help with patient thirst relief. [40]

CONCLUSIONS

Thirst is a prevalent, intense, and distressing symptom in ICU patients. A bundle of simple, inexpensive, and safe measures reduced TI and TD as well as xerostomia. Integrating this

practice with routine thirst assessment can relieve one of the most distressing symptoms experienced by critically ill patients.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Take-home message

Thirst is one of the most pervasive, intense, and under-treated symptoms in ICU patients. A thirst bundle consisting of oral swab wipes, sterile ice cold water sprays, and a lip moisturizer significantly decreased ICU patients' thirst and dry mouth and can be considered as a practice intervention for patients experiencing thirst.

Thirst in ICU patients is relieved by a thirst bundle containing oral swab wipes, sterile ice cold water sprays and lip moisturizer.

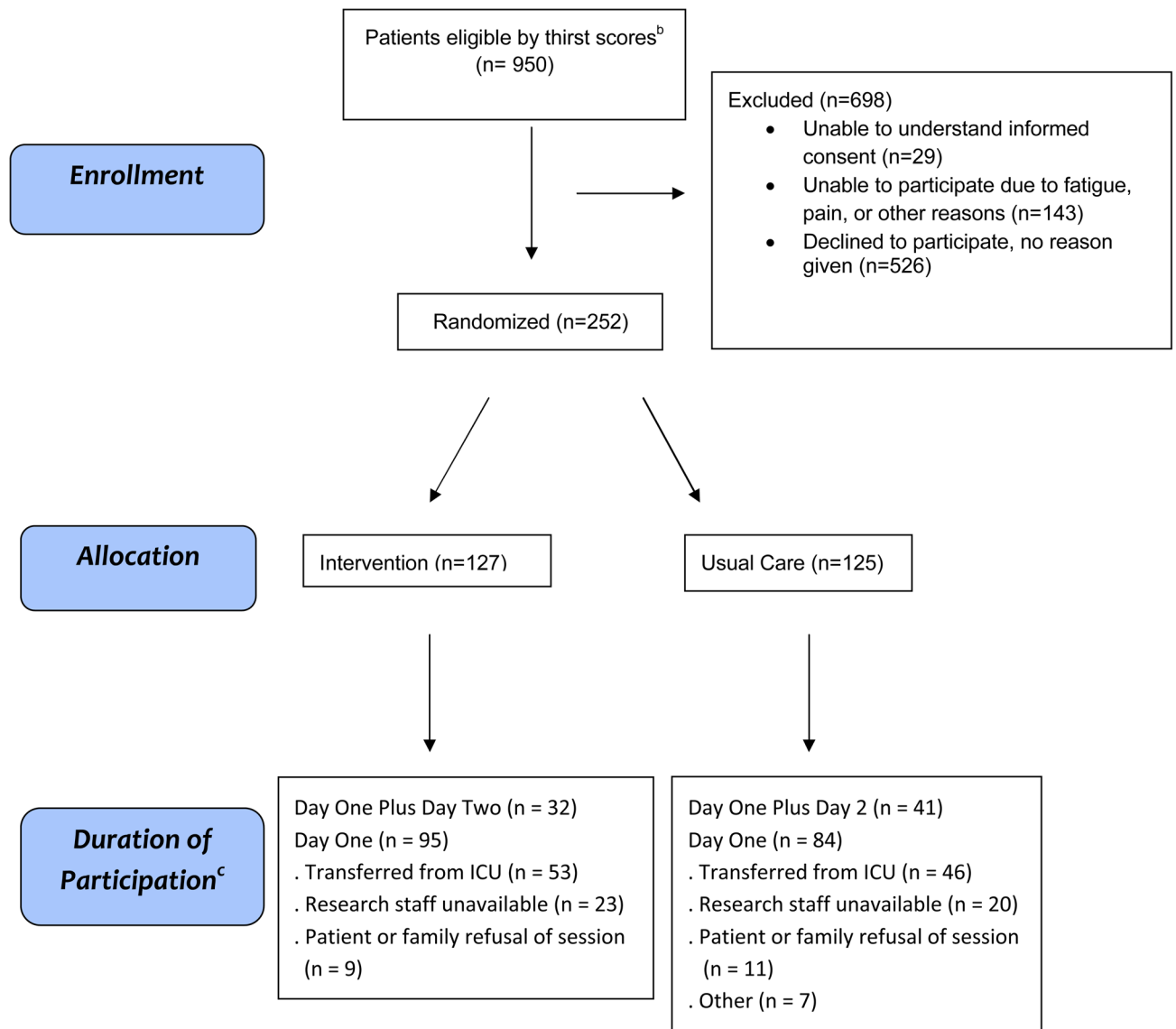


Fig. 1. Consolidated Standards of Reporting Trials (CONSORT)-style Flow Diagram of Screening,^a Recruitment, and Randomization

^aA total of 1417 patients were screened for thirst intensity and/or distress.

^b Thirst intensity and/or distress = 3 on 0 – 10 numeric rating scale.

^c Data from all patients used in analyses.

Table 1

Patient Baseline Demographic, Clinical and Biologic Characteristics

	Thirst Intervention Group (n = 127) (mean ±SD/median, IQR)	Thirst Usual Care (n = 125) (mean±SD/ median, IQR)
Age	54.5 ± 14.0/54 [46,64]	55.5 ± 15.0/56 [45,65]
Male Gender % (n)	53.5 (68)	56 (70)
Ethnicity % (n)		
Caucasian	64.6 (82)	68.8 (86)
African-American	7.1 (9)	12.8 (16)
Asian	7.9 (10)	4.8 (6)
Other	20.4 (26)	13.6 (17)
Hispanic % (n)	14.2 (18)	17.6 (22)
APACHE II	20.5 ± 8/20 [15,26]	20.2 ± 8.2/19 [14.5,25.5]
Disease Category % (n)		
Neurological	24.4 (31)	24.4 (31)
Cardiovascular	21.3 (27)	24.8 (31)
Respiratory	18.9 (24)	17.6 (22)
GI	18.1 (23)	19.2 (24)
Other	17.3 (22)	13.6 (17)
Total days in ICU	9.5 ± 12.2/5 [3,10]	9.5 ± 9.8/6 [4,12]
ICU day of enrollment	5.2 ± 5.8/3 [3,5]	5.6 ± 6.5/4 [3,7]
Died in ICU % (n)	3.9 (5)	2.4 (3)
Sessions completed*	3.1 ± 1.5/3 [2,3]	3.6 ± 1.7/3 [3,6]
Mechanically ventilated on study day % (n)	7.1 (9)	4.8 (6)
Osmolality (plasma)	297.1 ± 9.7/296 [289, 302] mOsm/kg	297.4 ± 13.1/295 [288, 302] mOsm/kg
Sodium	136.7 ± 3.4/137 [134, 135] mEq/l	136.8 ± 4.6/137 [134,139] mEq/l
Potassium	4.0 ± .49/4.0 [3.6,4.3] mEq/l	4.0 ± .45/3.9 [3.7,4.2] mEq/l
Glucose	137.5 ± 63.8/121 [104, 153] mg/dl	131.8 ± 52.3/121 [105,141] mg/dl
Blood urea nitrogen	23.1 ± 17.2/17.0 [10,33] mg/dl	23.9 ± 22.2/15.0 [9,30] mg/dl
Creatinine	1.3 ± 1.1/.97 [.66, 1.5] mg/dl	1.3 ± 1.0/.9 [.64,1.6] mg/dl
Morphine equivalency total dose per 24 hours	76 ± 133/20 [5,73]mg n = 98	67 ± 130/29 [13,54] mg n = 85
Furosemide total dose per 24 hours	67 ± 66/40 [20,80]mg n = 25	60 ± 55/40 [40,73]mg n = 40
Nil per os (NPO) orders (%)	35 (n=44)*	22 (n=27)
Received oral fluids (%)	65 (n=82)	77 (n=96)*
24 hour fluid intake (L)	2.4 ± 1.4/2.2 [1.4,3.0]	2.5 ± 1.7/2.1 [1.6,3.3]

* No significant difference between groups except for number of sessions completed [i.e., 0.5 session difference in number of sessions between groups (p = 0.02)]. Also, more Intervention patients had NPO orders, and fewer Intervention patients received oral fluids during study period.

Table 2

Thirst Intensity and Distress – Estimates of Fixed Effects Per Multilevel Linear Regression Analysis^a

Parameter	Estimate	Std. Error	df	t	Sig.	95% Confidence Interval lower limit	upper limit
Thirst Intensity							
Intercept	3.57	.22	331.06	16.25	<0.0005	3.14	4.00
Pre- to post procedure assessments ^b	2.30	.16	1435.70	14.65	<0.0005	2.0	2.60
Group ^c	1.11	.31	321.26	3.59	<0.0005	.50	1.72
Pre- to post procedure assessments by group ^d	-1.63	.22	1436.04	-7.60	<0.0005	-2.05	-1.21
Thirst Distress							
Intercept	3.15	.25	315.34	12.71	<0.0005	2.67	3.64
Pre- to post procedure assessments ^b	1.83	.16	1425.17	11.47	<0.0005	1.51	2.14
Group ^c	.53	.35	307.57	1.50	.135	-.16	1.21
Pre- to post procedure assessments by group ^d	-1.42	.22	1424.42	-6.48	<0.0005	-1.85	-.99

^aDependent Variables: thirst intensity and thirst distress.^bSimple effect for intervention group, post-score subtracted from pre-score.^cAverage difference between groups, pre to post.^dRepresents the interaction.

Table 3Estimated Mean^a Thirst Intensity and Thirst Distress Scores Collapsed Across Sessions and Days

		Thirst Intensity		
Observations by Group		Estimated Means (SE)	95% Confidence Intervals	
			lower limit	upper limit
Usual Care (n = 125)	Pre-thirst	5.3 (.22)	4.9	5.8
	Post thirst	4.7 (.22)	4.3	5.1
Intervention (n = 127)	Pre-thirst	5.9 (.22)	5.4	6.3
	Post thirst	3.6 (.22)	3.1	4.0
		Thirst Distress		
Observations by Group		Estimated Means (SE)	95% Confidence Intervals	
			lower limit	upper limit
Usual Care (n = 123)	Pre-thirst	4.1 (.25)	3.6	4.6
	Post thirst	3.7 (.25)	3.2	4.2
Intervention (n = 126)	Pre-thirst	5.0 (.25)	4.5	5.5
	Post thirst	3.2 (.25)	2.7	3.6

^aEstimated means from the multiple regression model.

Table 4Odds Ratios of Patients in the Intervention and Usual Care Groups Reporting Dry Mouth^a

	Dry Mouth					
	Odds Ratio	Std. Error	z	Sig.	95% Confidence Interval	
					lower limit	upper limit
Assessment: dry mouth ^b	.70	.15	-1.71	0.088	.46	1.05
Study Arm ^c	2.0	.96	1.44	0.151	.78	5.12
Assessment by group	.53 ^d	.17	-2.02	0.043	.29	.98

^aPer Multilevel Logistic Regression^bAssessment is the linear effect of time over three assessments of dry mouth.^cStudy Arm: Usual Care or Intervention groups^dReciprocal of 0.53 = 1.89 = odds of Usual Care group reporting dry mouth compared to the Intervention group for each additional assessment.