

# A Randomised Controlled Trial of Chewing Gum to Relieve Thirst in Chronic Heart Failure (RELIEVE-CHF)

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## Background

Thirst is a common and troublesome symptom of patients with chronic heart failure (CHF). To date, there are no interventions to help alleviate thirst in this cohort. Chewing gum is a novel intervention, which has been tested in people undergoing haemodialysis, also prescribed with a fluid restricted therapy. The aim of this study was to determine the effect of chewing gum on the level of thirst in the short-term (average of 24 hours each day for 4 days) and in the longer-term (Days 7, 14 and 28) individuals with CHF.

## Methods

Seventy-one (71) individuals with CHF on oral loop diuretics were randomised to chewing gum (n=36) or control (n=35) for 2 weeks. Both groups were assessed for their level of thirst at Days 1–4, 7, 14 and 28.

## Results

Significant improvements in the level of thirst of those who received chewing gum compared to the control group at Day 4 (p=0.04) and Day 14 (p=0.02) were observed.

## Conclusion

Chewing gum provided relief from thirst in the short-term and in the longer term. This trial provides important information to inform future clinical trials on ways to relieve thirst.

## Keywords

Randomised controlled trial • Chronic heart failure • Thirst • Chewing gum

## Introduction

Chronic heart failure (CHF) is a common, progressive and debilitating syndrome affecting 2% of the population in the Western world [1,2]. Its prevalence continues to rise due to the increase in the ageing population and improvements in cardiovascular treatment. People with CHF experience a large number of symptoms such as dyspnoea and fatigue [1,2]. In addition to these specific symptoms, many patients also suffer from thirst [3,4].

In healthy individuals, thirst has a natural physiological function, maintaining appropriate fluid balance. In a chronic

state such as CHF, thirst becomes a very strong desire for drinking water that is difficult to ignore, which can impact on adherence to self-care practices such as fluid restriction [5,6]. As a result, CHF patients are frequently immersed in thoughts of being thirsty but not allowing themselves to quench this thirst causing a great deal of distress which negatively affect the patient's quality of life, and may lead to non-adherence to fluid restriction and subsequent weight gain (a sign of decompensation) [5,7].

A number of factors have been linked to the presence of thirst in CHF [4]. The prolonged neurohormonal activation observed in CHF increases the level of angiotensin—a potent

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activator of thirst [6,8,9]. Pharmacological therapy to reduce symptoms of congestion such as diuretics can also result in dehydration, which further enhance the feelings of thirst [5,10,11]. Fluid restriction and high levels of anxiety may also increase patients' perceived thirst.

There are several studies investigating the effect of liberal fluid intake on thirst in participants with CHF, with inconclusive results [12]. However, a crossover study of 65 participants undergoing haemodialysis found chewing gum to be more effective in reducing thirst than artificial saliva in the Thirst Dialysis Inventory ( $5.5 \pm 2.7$  vs.  $3.3 \pm 2.6$ ;  $p < 0.001$ ) [13,14]. This effect may be explained by the saliva stimulating capacity of chewing gum. While the study was not conducted in CHF, the thirst experienced by patients undergoing haemodialysis is also caused by either an imbalance in fluid regulation due to their condition or a fluid restricted diet which is very similar to patients with CHF. As such, chewing gum was considered a useful intervention to alleviate thirst which warrants evaluation.

The aims of this study were to determine the effect of chewing gum on:

1. The level of thirst in the short-term (average of 24 hours each day for 4 days)
2. The level of thirst in the longer-term (at Days 7, 14 and 28)

## Materials and Methods

### Study Design and Setting

The study was a prospective, randomised, open label, design with two arms a) chewing gum vs. b) control (no chewing gum). All participants were followed up for 4 weeks. This trial was conducted at a medium-sized teaching hospital in Sydney, Australia.

### Ethical Considerations

Ethics approval was received from the Human Research Ethics Committee of the institution (14/136). This trial was registered on the Australian New Zealand Clinical Trials Registry (ACTRN12614000943640).

### Participants

Patient inclusion criteria were: i) aged  $\geq 18$  years; ii) primary or secondary diagnosis of CHF as per the National Heart Foundation and European Society of Cardiology guidelines; iii) receiving oral loop diuretics (based on the literature, participants on diuretics are often dehydrated and have increased feelings of thirst); and iv) able to safely chew and swallow. Patients were ineligible if they were: i) regular gum chewers (defined based on how often they chewed gum i.e. more than once a day); ii) on intravenous inotropes (however, they were eligible once the intravenous inotrope was ceased); iii) with restricted chewing and/or swallowing due to dysphagia or other impairment; or iv) unable to provide informed consent.

### Procedures

Potential participants were identified through inpatient lists and outpatient clinic lists. The trial co-ordinator approached the patients and invited them to participate in the study. Participants were screened against the inclusion and exclusion criteria. Once consented, baseline data including demographic profile, clinical status, comorbidities, results of their physical examination and level of thirst for each participant were collected.

### Randomisation

After informed consent had been obtained and baseline data collected, the participants were randomised 1:1 into either the intervention group (chewing gum) or the control group (no chewing gum) using a block randomisation and computer generated random numbers. They were then informed verbally of their group allocation. The study investigators did not have access to the randomisation schedule and were blinded to the group allocation prior to randomisation.

### Intervention

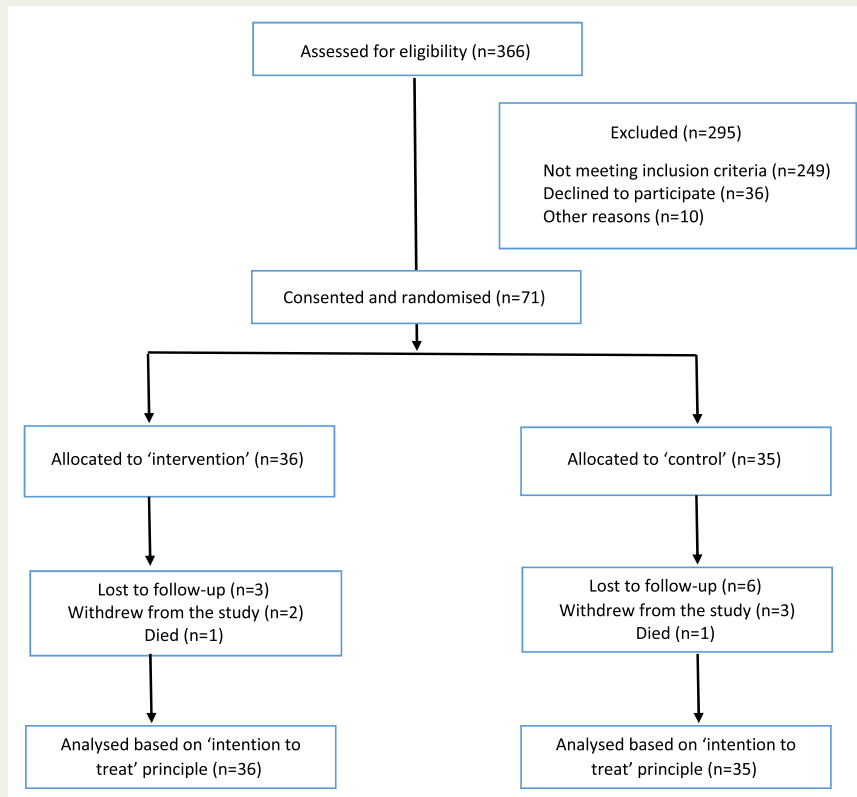
Participants in the intervention group were given 14 packets of Xylitol Epic Dental LLC (Epic Dental, Murray, UT, USA) peppermint flavour chewing gum over the 2-week study period. They were instructed to chew the gum gently, for at least 10 minutes, six times a day and as desired throughout the day when the mouth felt dry or when they were thirsty [13,14].

Participants in the control group were not provided with any chewing gum. They were instructed to continue with their normal strategies to relieve thirst. During the 2-week intervention, all participants completed a Visual Analogue Scale (VAS) and a Numeric Rating Scale (NRS) to rate their level of thirst each day for 4 days (Days 1–4), at days 7, 14 and 28. The study investigator collected the completed questionnaires from the participants' in hospital at 2 weeks and 4 weeks. If the participant was discharged before conclusion of the 2-week intervention, they were asked to continue on with the intervention at home. They then received a phone call to collect these measurements. Participants recruited from the outpatient clinic received a phone call at 2 weeks and 4 weeks where they were asked to report their thirst.

After the 2-week intervention, if participants perceived there had been any benefit in the use of chewing gum and they wished to continue using the gum, they were allowed to do so. However after the 2-week intervention period, participants were not provided with any more chewing gum. At 4 weeks (Day 28) after the intervention, participants were asked if they were continuing to use the chewing gum to relieve their thirst, what their perceived usefulness of the intervention in alleviating thirst and if they experienced any adverse events.

### Measures

The demographic information collected included patient's age and sex. Patient's clinical status, comorbidities and previous



**Figure 1** Consort flowchart of Randomised controlled trial of chewing gum to relieve thirst in Chronic Heart Failure (RELIEVE-CHF).

physical examination were also obtained. The Visual Analogue Scale with anchors 'no thirst at all' and 'worst thirst imaginable' was administered at baseline and at Day 1–4, 7, 14 and 28. Participants were asked to rate their thirst by placing a mark on the line corresponding to their current level of thirst. The distance along the line from the 'no thirst at all' marker is then measured with a ruler giving a score out of 100.

The Numeric Rating Scale [15] was also administered at baseline and at Days 1–4, 7, 14 and 28. Participants were asked three questions 'How is your thirst now?', 'How has your thirst been in the last 24 hours on average?' and 'What is the worst your thirst has been in the last 24 hours?'. They then rated their level of thirst by shading a circle corresponding to a number on a horizontal scale from 1 to 10 anchored at either end with a statement ('no thirst at all' = 1 and 'worst thirst imaginable' = 10) for the first two questions. For question 3, participants rated their level of thirst using a Likert scale (None, Mild, Moderate and Severe). Both measures were used to assess thirst intensity.

Due to certain disadvantages to the VAS, two different measures of thirst intensity were used in this study. While the VAS can be quickly administered, it is more demanding and requires greater cognitive skills (concentration, understanding and language skills) compared to the NRS. In addition, it is often difficult for some patients to convert a very subjective sensation such as thirst to a straight line [16].

Mistakenly placing an  $\times$  or a circle across the line may result in invalid results [17].

At 4 weeks (Day 28) after the intervention, participants in the intervention group completed a questionnaire created by the investigators. They were asked 'What their perception is of the usefulness of chewing gum in relieving thirst?' Participants rated the usefulness of chewing gum using a Likert scale (No use, Some use, Unsure, Useful and Very useful). They were asked an open-ended question 'Are you continuing to use chewing gum to relieve your thirst?' If they answered 'No', they were asked to provide a reason. They were also asked if they experienced any adverse events from chewing gum.

### Sample Size Calculation

Based on previous assessment of thirst, the estimated baseline level of thirst was  $5 \pm 2$ . To detect a  $1 \pm 2$  difference, an estimated sample size of 65 per group is needed with a two-sided 5% significance level and 81% power. When taking into account a loss to follow-up of 10% per group, 144 participants (72 per group) were required to be enrolled in this study.

### Statistical Analysis

Descriptive statistics summarised the baseline demographics and clinical characteristics of the overall sample and groups

**Table 1** Baseline characteristics of the 71 RELIEVE-CHF participants.

Characteristics	Total (n=71)	Intervention Group (n=36)	Control Group (n=35)	P-value
Age, mean (SD) yr	53.5 (13.8)	53.5 (12.7)	53.5 (15.1)	0.899
Sex (Male/Female) %	(63%/37%)	(61%/39%)	(66%/34%)	0.687
Body mass index, mean (SD)	27 (5)	28 (6)	26 (4)	0.028 <sup>a</sup>
Ejection fraction, mean (SD)	33 (15)	37 (17)	29 (12)	
Systolic pressure, mean (SD) (mm/Hg)	134 (20)	117 (22)	111 (17)	0.299
Diastolic pressure, mean (SD) (mm/Hg)	68 (10)	70 (11)	66 (8)	0.099
NYHA class %				1.000
Class I/II	52 (74%)	27 (75%)	25 (71%)	
Class III/IV	18 (26%)	9 (25%)	9 (26%)	
Admission status %				0.778
Inpatient	20%	19%	23%	
Outpatient	80%	81%	77%	
Comorbidities, n (%)				
Hypertension	14 (20%)	9 (25%)	5 (14%)	0.371
Myocardial infarction	13 (18%)	5 (14%)	8 (23%)	0.540
Diabetes mellitus	22 (31%)	11 (31%)	11 (31%)	1.000
Coronary artery disease	15 (21%)	6 (17%)	9 (26%)	0.561
Lung disease	10 (14%)	3 (8%)	7 (20%)	0.306
Charlson Index, mean (SD)	2.0 (1.5)	2.1 (1.6)	2.0 (1.4)	0.715
AKPS, mean (SD)	8.3 (1.2)	8.2 (1.0)	8.4 (1.3)	0.379
Prescribed medications %				
ACEIs+ARBs	34 (48%)	17 (47%)	17 (48.5%)	0.314
Beta blockers	46 (65%)	23 (64%)	23 (66%)	1.000
Diuretic dose %				0.078
Low diuretic dose (<40 mg/d)	3 (5%)	0 (0%)	3 (9%)	
High diuretic dose (≥40 mg/d)	61 (95%)	32 (89%)	29 (91%)	
Fluid restriction %	60 (84%)	32 (89%)	28 (80%)	0.309
Sodium, mean (SD) (mmol/L)	139 (3)	139 (3)	139 (4)	0.429
Potassium, mean (SD) (mmol/L)	4.3 (0.5)	4.3 (0.4)	4.3 (0.5)	0.948
Plasma urea (SD) (mmol/L)	9.9 (4.5)	9.4 (4.5)	9.1 (4.5)	0.423
Creatinine, mean (SD) (μmol/L)	119 (45)	114 (36)	124 (53)	0.492
eGFR, mean (SD)	59 (19)	61 (20)	57 (19)	0.621

Abbreviations: NYHA, New York Heart Association; AKPS, Australia-modified Karnofsky Performance Scale; ACE, angiotensin converting enzyme; ARBs, angiotensin receptor blockers; SD, standard deviation; RELIEVE-CHF, Randomised controlled trial of chewing gum to relieve thirst in Chronic Heart Failure.

<sup>a</sup>Statistical significance.

(intervention vs. control). The level of thirst in the first 4 days was chosen as the primary outcome. The reason for this is purely based on the likelihood that if the intervention (chewing gum) does alleviate thirst, the effect will be seen within the first 4 days compared to drug interventions which require more time and are dependent on factors such as concentration.

The main analysis was based on the intention to treat principle. Multiple imputation was used to analyse patterns and generate possible values for missing data; creating several "complete" sets of data and a pooled output which estimates the results of the original dataset if it had no missing values [18]. A pooled output of the five imputations

(default) was used to obtain the outcome scores at baseline to Day 28. Using the pooled output, the change in mean scores of VAS and NRS at Days 4 and 14 were calculated. An analysis of covariance was also performed on the primary endpoint (level of thirst at Day 4) to control for any confounding variables. A sensitivity analysis was performed on the 'completers' (those who completed the primary endpoint) without imputed data against the main analysis [19]. An independent sample t-test was used to compare the scores over time of the overall sample and within groups and between baseline and each follow-up point. All analyses were two tailed and p-value of <0.05 was considered statistically significant.

**Table 2** Baseline thirst measurements of the 71 RELIEVE-CHF participants.

Outcome Measures	Scores at Day 0
Visual Analogue Scale	43.9±19.8
Numeric Rating Scale	
<i>How is your thirst now?</i>	4.2±2.1
<i>How has your thirst been in the last 24 hr?</i>	4.7±1.8
<i>What is the worst your thirst has been in the last 24 hr?</i>	
None	4 (5.7%)
Mild	29 (41%)
Moderate	30 (43%)
Severe	7 (10%)

Abbreviations: RELIEVE-CHF, Randomised controlled trial of chewing gum to relieve thirst in Chronic Heart Failure.

## Results

Between November 2014 and September 2015, 366 individuals were screened for eligibility, and 107 were identified as eligible to participate in the study. Of the 295 who were excluded, 249 did not meet the inclusion criteria, 36 refused to participate and 10 were participating in another RCT at time of recruitment. Seventy-one (71) individuals were randomised (36 to the intervention group and 35 in the control group). Due to the slower than expected recruitment, the investigators made the decision to stop the trial in September 2015.

Sixteen (16) participants (six in the intervention group and 10 in the control group) were unable to be followed-up, resulting in a dropout rate of 23%. Nine (9) did not return follow-up calls, two died and five withdrew from the study due to personal reasons or dislike of the chewing gum. Therefore, the follow-up and regime compliance of this study was 78%. With the use of the 'intention to treat' principle, all participants were analysed in their groups and missing data were imputed as previously described. The flow of participants through the study is presented in Figure 1.

## Baseline Demographics and Clinical Characteristics

Table 1 shows the baseline demographics and clinical characteristics of 71 participants enrolled in this study. Among the sample, 63% (n=45) were male; with a mean age of 53.5±13.8 years; predominantly New York Heart Association (NYHA) class I/II and had a mean ejection fraction of 33%±15. The majority were on high doses of diuretics (≥40 mg/d) (95%; n=61) and on fluid restriction (84%; n=60). There were no significant differences in baseline and clinical characteristics between the groups, except for body mass index, (BMI) (28±6 vs. 26±4; p=0.028).

Table 2 presents the baseline thirst measurements for all participants. The level of thirst was measured by the VAS and

the NRS. The majority of the study participants (n=30; 43%) were moderately thirsty represented by the mean VAS score of 43.9±19.8 mm and NRS score of 4.7±1.8. There was no statistical significant difference in the level of thirst between the intervention and the control group (p=0.341) at baseline.

## Outcomes

Table 3 presents the thirst scores for all time points per group. Participants in the intervention group had a steady decrease in their level of thirst for both the VAS and NRS compared to the control group.

## Primary Outcome

### Change in the level of thirst at Day 4

The VAS scores at Day 4 of the intervention group significantly decreased compared to the control group (11±14 mm vs. 0.5±16.0 mm; p=0.04). The intervention group also showed a significant decrease in their NRS score compared to the control group (0.8±1.8 mm vs. 0.3±2.0 mm; p=0.019). Due to the significant difference in BMI between the groups (28±6 vs. 26±4; p=0.028), an analysis of covariance was performed on the primary outcome (level of thirst at Day 4). There were no statistically significant differences in the level of thirst at Day 4 between the groups when adjusted for BMI (p=0.165).

## Secondary Outcomes

### Change in the level of thirst at Day 7, 14 and 28

Table 4 presents the change in VAS and NRS scores for all time points per group. The VAS and NRS (How has your thirst been in the last 24 hours on average?) scores at Day 7 showed a statistical significant decrease in the intervention group compared to the control group (p=0.001 and p=0.05). At Day 14, both the VAS and NRS (How is your thirst now?) scores of the intervention group also significantly decreased at Day 14 (13.5±15.2 mm vs. 2.0±20.3 mm; p=0.02) and (0.7±1.5 mm vs. 0.2±1.8 mm; p=0.02), respectively (Figure 2). This continued at Day 28 with the VAS and NRS (How has your thirst been in the last 24 hours on average?) scores showing statistical significant reductions in the intervention group compared to control.

## Sensitivity Analysis of the Primary Outcome (Day 4)

The VAS scores at Day 4 of those in the intervention group significantly decreased for the 'completers' (p=0.04) and 'imputed' cohort (p=0.007). The NRS scores of the intervention group also demonstrated a significant decrease for the 'completers' (p=0.018) and 'imputed' (p=0.027) cohort (Figure 3).

## Usefulness and Continued Use of Chewing Gum

At least 31% (n=11) found chewing gum useful while others found no use (25%; n=9). On the other hand, 53% of

**Table 3** Thirst scores for all time points per group.

Outcomes	Intervention						
	Day 1	Day 2	Day 3	Day 4	Day 7	Day 14	Day 28
Visual Analogue Scale, mean (SD)	43.4 (17.3)	39.0 (17.8)	41.0 (19.2)	37.9 (16.2)	34.4 (17.0)	34.5 (16.6)	36.1 (18.0)
Numeric Rating Scale-How is your thirst now, mean (SD)	4.0 (1.8)	4.3 (1.8)	4.0 (1.6)	3.7 (1.5)	4.0 (1.5)	3.8 (1.4)	3.7 (1.6)
Numeric Rating Scale-How has your thirst been in the last 24 hr on average, mean (SD)	4.5 (1.7)	4.5 (1.5)	4.7 (1.8)	4.2 (1.6)	4.0 (1.5)	3.9 (1.4)	3.8 (1.5)
What is the worst your thirst has been in the last 24 hr, N (%)	1.5 (0.5)	1.4 (0.5)	1.5 (0.7)	1.3 (0.6)	1.2 (0.5)	1.2 (0.5)	1.2 (0.6)
None	1 (2.8)	1 (2.8)	1 (2.8)	2 (5.6)	2 (5.6)	1 (2.8)	1 (2.8)
Mild	13 (36.1)	15 (41.7)	14 (38.9)	16 (44.4)	17 (47.2)	19 (52.8)	21 (58.3)
Moderate	16 (44.4)	14 (38.9)	10 (27.8)	10 (27.8)	10 (27.8)	8 (22.2)	4 (11.1)
Severe	0 (0)	0 (0)	4 (11.1)	1 (2.8)	0 (0)	0 (0)	2 (5.6)
	Control						
Visual Analogue Scale, mean (SD)	39.9 (22.6)	40.3 (22.9)	39.5 (22.7)	41.5 (20.4)	42.2 (19.9)	39.8 (21.1)	39.8 (21.1)
Numeric Rating Scale-How is your thirst now, mean (SD)	4.3 (1.9)	3.7 (1.8)	4.3 (2.1)	4.4 (1.9)	4.1 (1.7)	4.3 (1.8)	4.5 (2.1)
Numeric Rating Scale-How has your thirst been in the last 24 hr on average, mean (SD)	4.4 (2.0)	4.4 (1.9)	4.5 (1.9)	4.7 (1.8)	4.5 (1.7)	4.4 (1.8)	4.4 (1.9)
What is the worst your thirst has been in the last 24 hr, N (%)	4.4 (2.0)	1.6 (0.7)	1.6 (0.6)	1.6 (0.5)	1.7 (0.6)	1.5 (0.7)	1.6 (0.6)
None	1 (2.9)	2 (5.7)	1 (2.9)	9 (25.7)	1 (2.9)	2 (5.7)	1 (2.9)
Mild	9 (25.7)	7 (20.0)	8 (22.9)	15 (42.9)	6 (17.1)	9 (25.7)	7 (20.0)
Moderate	14 (40.0)	15 (42.9)	14 (40.0)	1 (2.9)	16 (45.7)	13 (37.1)	14 (40.0)
Severe	1 (2.9)	1 (2.9)	2 (5.7)	0 (0)	2 (5.7)	1 (2.9)	1 (2.9)

**Table 4** Change in thirst scores for all time points per group.

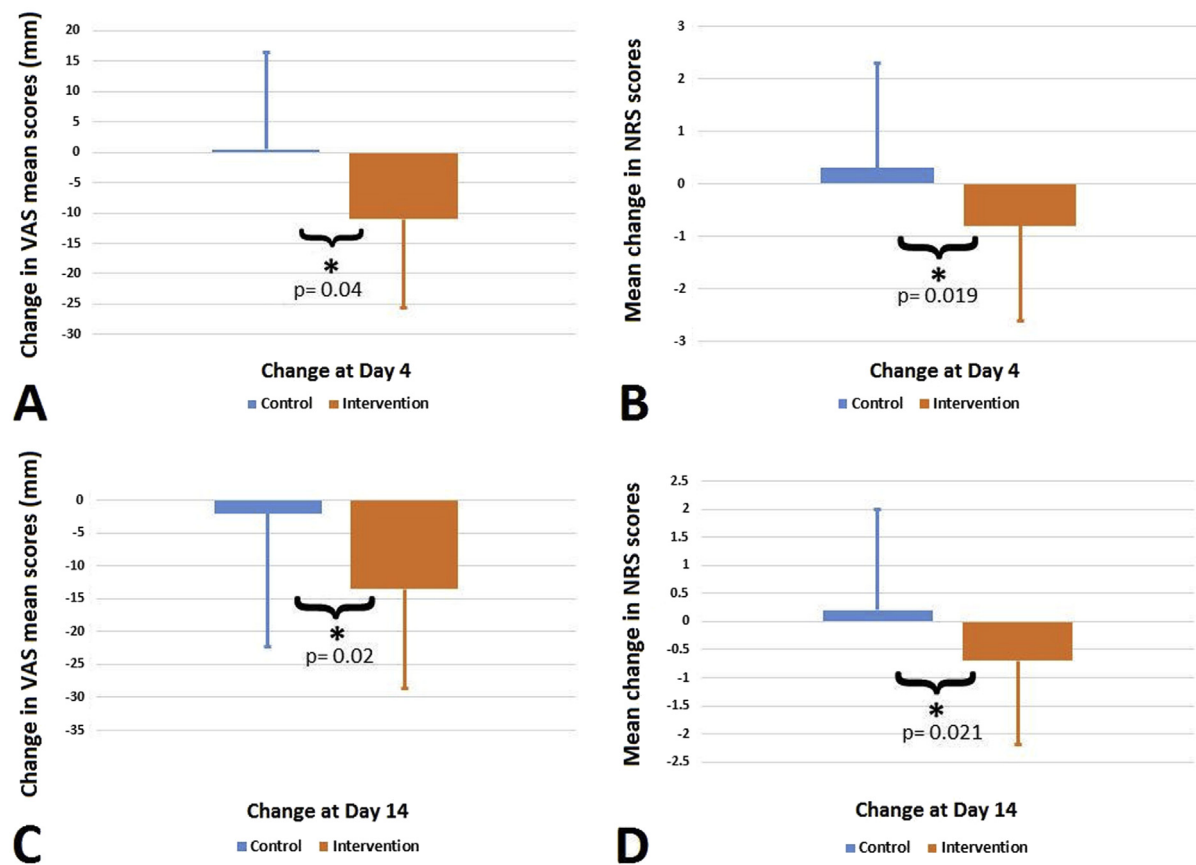
Visual Analogue Scale			
	Intervention	Control	P-value
Day 4	-11	0.5	0.04 <sup>a</sup>
Day 7	-10.4	-0.7	0.001 <sup>a</sup>
Day 14	-13.5	-2	0.015 <sup>a</sup>
Day 28	-9	0.9	0.001 <sup>a</sup>
Numeric Rating Scale-How is your thirst now?			
Day 4	-0.8	0.3	0.019 <sup>a</sup>
Day 7	-0.6	0.09	0.199
Day 14	-0.7	0.2	0.021 <sup>a</sup>
Day 28	0.8	0.35	0.08
Numeric Rating Scale-How has your thirst been in the last 24 hours on average?			
Day 4	-0.6	-0.1	0.116
Day 7	0.79	-0.33	0.05 <sup>a</sup>
Day 14	-0.9	-0.5	0.093
Day 28	-1.05	-0.5	0.02 <sup>a</sup>

<sup>a</sup>Statistical significance.

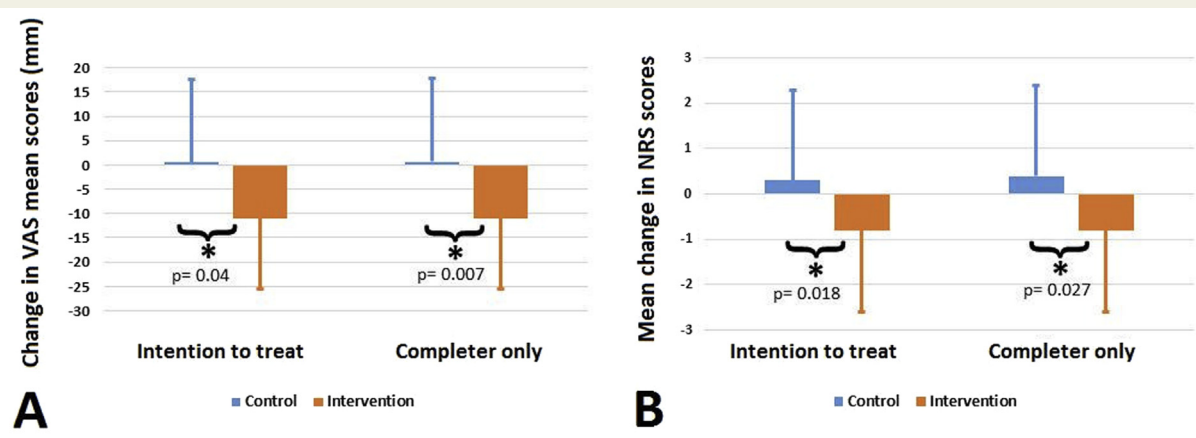
participants continued to chew gum (n=19) after the 2-week intervention period while others did not continue using chewing gum (25%; n=9). Less than a quarter did not complete this question.

## Discussion

With the rise in the prevalence of thirst in CHF, there is an increasing need for simple interventions such as chewing gum to address this significantly overlooked problem. Randomised controlled trial of chewing gum to relieve thirst in Chronic Heart Failure (RELIEVE-CHF) is a novel approach to thirst management in CHF. It is the first study to investigate the effect of chewing gum in patients with CHF. In this study, we demonstrated that chewing gum provided patients' with significant relief from thirst. This similar trend is also seen in other studies investigating chewing gum in a different patient population [13,20]. Although promising, several aspects must be considered when comparing the results of these studies. The dimension of thirst measured in this study is thirst intensity compared to the other two studies which measured the frequency of thirst [13,20]. Thirst intensity and frequency differ from each



**Figure 2** (A) Change in VAS mean scores of the intervention vs. control group at Day 4. (B) Change in mean NRS scores of the intervention vs. control group at Day 4. (C) Change in mean VAS scores of the intervention vs. control group at Day 14. (D) Change in mean NRS scores of the intervention vs. control group at Day 14. \* Statistical significance. Abbreviations: VAS, visual analogue scale; NRS, numeric rating scale.



**Figure 3** (A) Change in mean VAS scores between the 'intention to treat' and the 'completers only' at Day 4. (B) Change in mean NRS scores between the 'intention to treat' and the 'completers only' at Day 4. \* Statistical significance. Abbreviations: VAS, visual analogue scale; NRS, numeric rating scale.

other where one dimension quantifies the strength of thirst while the other on how often thirst occurs [21]. These differences may also be attributable to the instruments used to measure thirst in each study; our study utilised the VAS and NRS as opposed to a Dialysis Thirst Inventory [13] or a non-validated 19 multiple choice tool [20] used by the other two. Scoring and measurement of thirst in both scales are completely different to the VAS and the NRS which make comparisons between studies challenging.

In terms of patients' perception of the intervention, 31% of participants found chewing gum useful in relieving thirst which agrees with findings from a similar intervention in haemodialysis patients and like our study, most of the participants were willing to continue to use chewing gum after the study period [14]. However, neither study knows for how long the participants continued to use it. Aside from relief from thirst, participants found that chewing gum provided a distraction from drinking water; it tasted pleasant and freshened their breath, which also reflects the findings of Bots *et al.* (2005).

While this study has demonstrated that chewing gum can reduce patients' level of thirst, our study has also highlighted some challenges in implementing the use of chewing gum in clinical practice based on our experiences during recruitment. People with CHF are predominantly elderly and thus the use of dentures is common. There are also negative social beliefs attached to chewing gum within this demographic. Therefore, despite clinical effectiveness, lack of patient acceptance remains the barrier to implementation. This also highlights the importance of exploring the use of another intervention to provide patients with a variety of strategies to manage thirst more suited to their personal preference.

## Limitations

Due to the numerous difficulties encountered during recruitment, the study had to be stopped (short duration of the trial) and was only able to recruit approximately half ( $n=71$ ) of the planned 144 participants. Despite this, the study results consistently demonstrated significant difference in participants' level of thirst between groups based on our primary endpoint 'intention to treat' analysis (imputed missing data) and sensitivity analysis (completers only). This study is still the largest trial of testing the use of chewing gum to relieve thirst to date.

Another limitation is the inclusion of participants who did not have thirst at baseline. Most of the participants had thirst but for the small number ( $n=4$ , 5.7%) who did not report thirst, as this was a one-time assessment we did not wish to exclude participants with HF who were on a diuretic regime, and therefore likely to experience thirst from being included in the study as the absence of thirst at the time of the assessment may have been due to participant just having had a drink or brushed their teeth etc.

## Conclusions

Innovative strategies such as the use of chewing gum are important within the growing prevalence of thirst in CHF. Chewing gum is a simple management strategy; one that is low cost and easily accessible. Our findings show significant improvements in participants' level of thirst after chewing gum, comparable to another study in the literature. Although, we have shown that chewing gum relieves thirst in CHF patients, social stigma and attitudes towards chewing gum are important aspect for consideration in its implementation in clinical practice. RELIEVE-CHF will add to the evidence-based on the use of chewing gum to relieve thirst in CHF and inform the design of future clinical trials on ways to alleviate thirst.

## Conflicts of Interest

None declared.

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