

Study Protocol

Official title of the study: Effect of Chewing Gum in Hemodialysis Patients

NCT number: NCT04142216

Date of document: April 20, 2020

Objective: The aim of this study was to investigate the effect of chewing gum on dry mouth, interdialytic weight gain (IWG) and intradialytic symptoms in hemodialysis (HD) patients.

Design: Prospective, randomized controlled single-blind trial

Methods: The study was conducted in accordance with the Declaration of Helsinki. Permission was obtained from the local ethics committee (Meeting Date: 07/16/2019, Decision No: 2019-7) and the relevant institutions in addition to written consent from the subjects.

This study was conducted with patients treated at two HD units of two public hospitals between October 2019 and January 2020. Patients in the experimental group chewed gum for three months. The patients in the control group did not chew gum and there was no intervention. The 2010 CONSORT Statement for Randomized Trials of Non-Pharmacological Treatments was used as a guide to report the study.

All the patients who had been treated for at least six months with sessions three days a week for four hours each, were aged 18 years or more, had no psychiatric disorder preventing communication, stated experiencing dry mouth, and volunteered to participate were included in the study. Patients who had previously received chemotherapy or radiotherapy; who had dementia, salivary gland infection, oral and/or dental discomfort that would prevent chewing gum; who were using antidepressants, antipsychotics, benzodiazepine or opioids; and who did not volunteer to participate were excluded.

Statistical Analysis Plan

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Outcome measures

Primary outcomes

Change from Baseline Intradialytic weight gain: Interdialytic weight gain was defined as the difference between the predialytic weight and weight at the end of the previous dialysis session.

Change from Baseline Dry Mouth at three months: It will be assessed three times at the end of the dialysis session with Visual Analogue Scale. Visual Analogue Scale ranging from 0 (no dry mouth) to 10 (worst dry mouth). Dry mouth increases the score increases. The high point describes bad outcome.

Change from Baseline Dry Mouth at three months: It will be assessed three times at the end of the dialysis session with Visual Analogue Scale. Visual Analogue Scale ranging from 0 (no dry mouth) to 10 (worst dry mouth). Dry mouth increases the score increases. The high point describes bad outcome.

Change from Baseline Dry Mouth at three months: It will be assessed two times at the end of the dialysis session with sample of saliva. Saliva flow rate will be measured. Saliva flow rate is presented with "ml".

Change from Baseline Intradialytic symptoms at three months: It will be assessed with "Dialysis Symptom Index". Using this scoring system, the minimum possible total severity score was 0 if none of the 30 symptoms was present and the maximum potential. Score was

150 if all of the 30 symptoms were reported and rated as "very much bothersome". The minimum value is "0" and the maximum value is "150".

Secondary outcomes

Change from Baseline Anxiety at three months: It will be assessed with Hospital Anxiety and Depression Scale. This scale, which has a two-factor structure is comprised of 14 items. Seven of these items assess the anxiety status and the remaining seven assess depression. Each item is scored on a four-point scale. Total score ranges between 0 and 21 for anxiety and depression. Scores between 0 and 7 indicate normal emotional status.

Change from Baseline Fluid Control at three months: It will be assessed with "Fluid Control Scale in Hemodialysis Patients". the scale had 24 items and three subdimensions,namely, knowledge, behavior, and attitude. The lowest score obtained from the scale was 24 and the highest score was 72, and the higher the score, the greater the compliance of the patients with fluid control.

Change from Baseline Depression at three months: It will be assessed with Hospital Anxiety and Depression Scale. This scale, which has a two-factor structure is comprised of 14 items. Seven of these items assess the anxiety status and the remaining seven assess depression. Each item is scored on a four-point scale. Total score ranges between 0 and 21 for anxiety and depression. Scores between 0 and 7 indicate normal emotional status.

Statistical analysis

The Statistical Package for Social Sciences (SPSS Inc., Chicago, IL., USA) 22.0 software program was used in the statistical analysis of the data obtained during the study. The compliance of the measurement values with a normal distribution was investigated with the "Shapiro-Wilk Test". Mean±standard deviation, median, and interquartile range (IQR) were used to present the descriptive statistics of continuous numerical variables, and number (n)

and percentage (%) were used to present the categorical variables. Comparisons of the data not showing a normal distribution were made by using the “Mann-Whitney U Test”, “Chi-Square Test”, and “Fisher’s Exact Test” while comparisons of the data showing a normal distribution were made using “Student’s *t* Test” and the “Paired Samples Test”. Variables measured at two different times in the dependent groups were compared with the “Wilcoxon Two-sample Paired Test”. The “Repeated-Measures Analysis of Variance” test was used to compare the measurements of the groups made at more than two different times. A *p* value <0.05 was considered statistically significant in statistical decisions.

Results

Title:	Change From Baseline Intradialytic Weight Gain	
► Description:	Interdialytic weight gain was defined as the difference between the pr...	
Time Frame:	up to 12 weeks	
▼ Outcome Measure Data ✓		
► Analysis Population Description		
Arm/Group Title	Control Group	Chewing Gum Group
► Arm/Group Description:	The patients will not chewing gum d...	The patients will be asked to chew ...
Overall Number of Participants Analyzed	22	22
Mean (Standard Deviation) Unit of Measure: kg	2.53 (0.80)	2.44 (0.95)

Title:	Change From Baseline Feeling of Thirst at Three Months	
► Description:	It will be assessed three times at the end of the dialysis session wi...	
	If reporting a score on a scale, please include the unabbreviated scale title, the minimum and maximum values, and whether higher scores mean a better or worse outcome.	
Time Frame:	At the end of the 1st, 6th, 12th week (3 hemodialysis sessions are done every week)	
▼ Outcome Measure Data ✓		
► Analysis Population Description		
Arm/Group Title	Control Group	Chewing Gum Group
► Arm/Group Description:	The patients will not chewing gum d...	The patients will be asked to chew ...
Overall Number of Participants Analyzed	22	22
Mean (Standard Deviation) Unit of Measure: score on a scale	5.04 (2.76)	1.72 (2.07)

Title:	Change From Baseline Dry Mouth at Three Months													
► Description:	It will be assessed three times at the end of the dialysis session with ... If reporting a score on a scale, please include the unabbreviated scale title, the minimum and maximum values, and whether higher scores mean a better or worse outcome.													
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Overall Number of Participants Analyzed	22	22												
Mean (Standard Deviation) Unit of Measure: units on a scale	5.04 (2.76)	1.72 (2.07)												

Title:	Change From Baseline Intradialytic Symptoms at Three Months													
► Description:	It will be assessed with "Dialysis Symptom Index". Using this scoring ... If reporting a score on a scale, please include the unabbreviated scale title, the minimum and maximum values, and whether higher scores mean a better or worse outcome.													
Time Frame:	At the end of the 1st and 12th week (3 hemodialysis sessions are done every week)													
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► Arm/Group Description:	The patients will not chewing gum d...	The patients will be asked to chew ...												
Overall Number of Participants Analyzed	22	22												
Mean (Standard Deviation) Unit of Measure: score on a scale	19.13 (13.71)	19.18 (15.27)												

Title:	Change From Baseline Anxiety at Three Months	
► Description:	It will be assessed with Hospital Anxiety and Depression Scale. This s... If reporting a score on a scale, please include the unabbreviated scale title, the minimum and maximum values, and whether higher scores mean a better or worse outcome.	
Time Frame:	At the end of the 1st and 12th week (3 hemodialysis sessions are done every week)	
▼ Outcome Measure Data ✓		
► Analysis Population Description		
Arm/Group Title	Control Group	Chewing Gum Group
► Arm/Group Description:	The patients will not chewing gum d...	The patients will be asked to chew ...
Overall Number of Participants Analyzed	22	22
Mean (Standard Deviation) Unit of Measure: score on a scale	8.18 (5.50)	8.40 (5.71)

Title:	Change From Baseline Fluid Control at Three Months	
► Description:	It will be assessed with "Fluid Control Scale in Hemodialysis Patients... If reporting a score on a scale, please include the unabbreviated scale title, the minimum and maximum values, and whether higher scores mean a better or worse outcome.	
Time Frame:	At the end of the 1st and 12th week (3 hemodialysis sessions are done every week)	
▼ Outcome Measure Data ✓		
► Analysis Population Description		
Arm/Group Title	Control Group	Chewing Gum Group
► Arm/Group Description:	The patients will not chewing gum d...	The patients will be asked to chew ...
Overall Number of Participants Analyzed	22	22
Mean (Standard Deviation) Unit of Measure: score on a scale	53.95 (6.06)	58.04 (4.82)

Title:	Change From Baseline Depression at Three Months	
► Description:	It will be assessed with Hospital Anxiety and Depression Scale. This s... If reporting a score on a scale, please include the unabbreviated scale title, the minimum and maximum values, and whether higher scores mean a better or worse outcome.	
Time Frame:	At the end of the 1st and 12th week (3 hemodialysis sessions are done every week)	
▼ Outcome Measure Data ✓		
► Analysis Population Description		
Arm/Group Title	Control Group	Chewing Gum Group
► Arm/Group Description:	The patients will not chewing gum d...	The patients will be asked to chew ...
Overall Number of Participants Analyzed	22	22
Mean (Standard Deviation) Unit of Measure: score on a scale	8.63 (4.90)	8.13 (4.31)