ISRCTN26299165 https://doi.org/10.1186/ISRCTN26299165

Effect of chewing gum on orthodontic pain, painkiller uptake and appliance breakages

Submission date 14/02/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 15/02/2024	**Overall study status** Completed	
Last Edited 15/02/2024	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims

Orthodontic fixed appliances are related to the experience of mild-to-severe pain and discomfort in patients undergoing treatment. Due to the unpleasant experience, there was an apparent poor compliance issue, with many discontinued orthodontic treatments. Various interventions are utilized to overcome pain during orthodontic treatments including the use of pain medications. However, concerns have been raised with regards to their long-term treatment side effects. Sugar-free chewing gum is one of the growing alternatives in the management of pain in orthodontic treatments. Current literature on the effectiveness of pain control by chewing gum is only limited to initial phase of orthodontic treatment and no study has been further conducted on a later stage of orthodontic treatment, such as using final stainless steel working archwire. Therefore, this randomised controlled trial aims to study the effects of chewing sugar-free gum on self-reported pain, use of analgesic medications and appliance breakages associated with the use of stainless steel working archwires.

Who can participate?

Healthy female patients aged 20-40 years old who are currently undergoing upper and lower fixed orthodontic treatment having upper and lower stainless steel archwires with no pain-related disease can participate.

What does the study involve?

Subjects are randomly allocated into two groups of 22 subjects each; chewing gum group (experimental group) and the control group. Subjects in the chewing gum group are instructed to chew gum for 5 minutes immediately after archwire placement. Subjects in both groups record their pain using Visual Analogue Scale (VAS) instrument at baseline before archwire placement, immediately after, and at 12, 24, 36, 48, 60 and 72 hours.

What are the possible benefits and risks of participating?

No specific risks involved. Chewing gum may serve as an adjunct for orthodontists for better pain management in their patients having stainless steel archwire.

Where is the study run from?
Klinik Pergigian Dr Fatain Indera Mahkota 3 & Department of Orthodontics, Kulliyyah of Dentistry (Kuantan, Malaysia)

When is the study starting and how long is it expected to run for?
October 2022 to December 2023

Who is funding the study?
International Islamic University Malaysia (IIUM)

Who is the main contact?
Cheong Joo Ming; alvinjooming@iium.edu.my

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr Joo Ming Cheong

ORCID ID
http://orcid.org/0000-0002-7487-7396

Contact details
Kulliyyah of Dentistry, International Islamic University Malaysia,
Jalan Istana, Bandar Indera Mahkota, Pahang
Kuantan
Malaysia
25200
+603 6421 5002
rescentre@iium.edu.my

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title

The effect of sugar-free chewing gum on self-reported orthodontic pain associated with stainless steel archwire placement

Study objectives
1. Sugar-free gum is associated with pain-relief effects in patients with stainless steel working archwires.
2. Sugar-free gum reduces the intake of analgesic medications in patients with stainless steel wire.
3. Chewing gum group is associated with increased frequency of appliance breakages compared to non-chewing gum group.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 14/02/2023, International Islamic University Malaysia Research Ethics Committee (IREC) (Kulliyyah of Dentistry, International Islamic University Malaysia, Jalan Istana, Bandar Indera Mahkota, Pahang, Kuantan, 25200, Malaysia; +60 168577697; alvinjooming@iium.edu.my), ref: IREC 2023-032

Study design
Multicenter interventional simple randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Dental clinic

Study type(s)
Treatment

Participant information sheet
See outputs table

Health condition(s) or problem(s) studied
Reducing orthodontic pain in patients with stainless steel archwire during orthodontic treatment

Interventions
Female participants are randomly allocated into either chewing gum group or control group using random table generation (WebPower Statistical power analysis online) and sealed envelope. Subjects in the chewing gum group are instructed to chew sugar-free gum (Wrigley's Extra, Malaysia) for 5 minutes followed by marking the pain level on the visual analogue scale (VAS) to assess pain at baseline (before placement of stainless steel archwires), immediately after placement (0 hour), at 12, 24, 36, 48, 60 and 72 hours after archwire placement. No chewing gum will be given to the control group.

Intervention Type
Other

Primary outcome measure
Self-reported orthodontic pain using a visual analogue scale (VAS) at baseline (before placement of stainless steel archwires), immediately after placement (0 hour), at 12, 24, 36, 48, 60 and 72 hours after archwire placement.

Secondary outcome measures
1. Analgesic uptake measured using self-reported questionnaire (frequency, type, dosage and timing of analgesics taken) during the 72-hour study period.
2. Appliances breakages (brackets/tubes/bands) measured using self-reported questionnaire during the 72-hour study period.

Overall study start date
20/10/2022

Completion date
02/12/2023

Eligibility

Key inclusion criteria
1. Healthy female aged 20-40 years old
2. Patients fitted with both upper and lower 0.019” x 0.025” rectangular stainless steel archwires on upper and lower pre-adjusted edgewise fixed orthodontic appliances treatment
3. Non-smoker
4. Patients with no craniofacial anomalies
5. No pain-related pathology or disease
6. Not receiving any form of analgesics
7. No oral surgery in the previous 4 weeks

Participant type(s)
Patient

Age group
Adult

Lower age limit
20 Years

Upper age limit
40 Years

Sex
Female

Target number of participants
80

Total final enrolment
44

Key exclusion criteria
1. Subjects who only had upper or lower stainless steel archwires
2. Subjects who receive any form of analgesics
3. Subjects who had oral surgery in the previous four weeks
4. Pregnant woman
5. Subjects who have previous orthodontic/orthognathic treatment
6. Subjects who have hypersensitivity reactions to aspirin or other NSAIDs including asthma, rhinitis or urticaria

Date of first enrolment
10/04/2023

Date of final enrolment
28/11/2023

Locations

Countries of recruitment
Malaysia

Study participating centre
Klinik Pergigian Dr Fatain Indera Mahkota 3
INDERA MAHKOTA 3 A-25 GROUND FLOOR DM, LORONG IM3/19, Bandar Indera Mahkota, Pahang
Kuantan
Malaysia
25200

Study participating centre
Department of Orthodontics, Kulliyyah of Dentistry, International Islamic University Malaysia (IIUM)
Jalan Istana, Bandar Indera Mahkota, Pahang
Kuantan
Malaysia
25200

Sponsor information

Organisation
International Islamic University Malaysia

Sponsor details
Kulliyyah of Dentistry, International Islamic University Malaysia
Jalan Istana, Bandar Indera Mahkota, Pahang
Kuantan
Malaysia
25200
+603 6421 6421
webmaster@iium.edu.my

Sponsor type
University/education

Website
https://office.iium.edu.my/ocd/

ROR
https://ror.org/03s9hs139

Funder(s)

Funder type
University/education

Funder Name
International Islamic University Malaysia

Alternative Name(s)
Universiti Islam Antarabangsa Malaysia, IIUM

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Malaysia

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/11/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publicly available repository (https://docs.google.com/document/d/1OAd-fjR0TI87DDauzcp3EQzeMvJsui8cNI8G86On52s/edit#heading=h.a1103o6boelk)
All the data analysis pertaining to descriptive and inferential (One-way Repeated Measure ANOVA & Chi-square) statistics are already made available in the provided link.

Consent from all participants have been obtained for data that will be used for publication purposes. All data have been made anonymized.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1	09/02/2023	15/02/2024	No	Yes
Protocol file	version 1	09/02/2023	15/02/2024	No	No