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Comparing four removable orthodontic devices and no orthodontic treatment in children with excessive overjet

Submission date 14/03/2020	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 30/04/2020	**Overall study status** Completed	
Last Edited 10/07/2023	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
Malocclusion means that the upper and lower teeth do not fit together well. This can cause problems with chewing and dental hygiene. Class II malocclusion (overjet) is where the upper jaw teeth are further forward than the lower jaw teeth. This is commonly caused by the lower jaw being underdeveloped or being positioned too far back. Class II malocclusion can be treated in growing children by wearing braces that encourage the lower jaw to grow or move forward. This study aims to compare three braces to eachother and to no treatment in correcting class II malocclusion in children before and during puberty.

Who can participate?
Children aged 17 years or under who need orthodontic treatment for class II malocclusion.

What does the study involve?
Participants who choose to delay wearing a brace will have X-rays at the start of the study and at 18 months. Those who choose to start treatment immediately will be randomly allocated to wear one of three braces. They will have X-rays at the start of the study and at the end of treatment.

What are the possible benefits and risks of participating?
Participants will benefit from correction of their malocclusion. There are no risks expected for those taking part in the study. The braces might be uncomfortable at the start.

Where is the study run from?
University of Turin Dental School (Italy)

When is the study starting and how long is it expected to run for?
June 2019 to December 2023

Who is funding the study?
University of Turin (Italy)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
0019079

Study information

Scientific Title
Dento-skeletal effects of removable functional appliances in class II growing patients: a randomized controlled trial

Acronym
TERFAC2

Study objectives
The aim of this study is to compare dento-skeletal effects of functional removable appliances in skeletal Class II malocclusion in growing patients at different stages of growth, according to cervical vertebral maturation method (CVM2 and CVM3), compared to untreated subjects.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/02/2020, Ethics Board of the City of Health And Science of Turin [Comitato Etico Interaziendale A.O.U. Città della Salute e della Scienza di Torino] (Corso Bramante 88/90, 10126 Turin, Italy; +39 011 6331633; comitatoetico@cittadellasalute.to.it), ref: 000127/2019

Study design
Single-centre randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Malocclusion

Interventions
Current interventions as of 19/01/2023:
In this randomized controlled trial, the sample will be composed of 4 arms: no treatment (patients that autonomously choose to delay the treatment), and 3 randomly assigned treatment arms (EF myofunctional device, Invisalign with mandibular advancement feature, Function Generating Bite arm, Twin Block arm) comprising 15 Caucasian growing class II subjects for each arm. The randomization will be generated using Randomizer software.

Previous interventions:
In this randomized controlled trial, the sample will be composed of 4 arms: no treatment (patients that autonomously choose to delay the treatment), and 3 randomly assigned treatment arms (EF myofunctional device, Invisalign with mandibular advancement feature, Function Generating Bite arm) comprising 15 Caucasian growing class II subjects for each arm. The randomization will be generated using Randomizer software.

Within the group treated, there will be two subgroups according to the cervical vertebrae maturation (CVM) stage of growth at the beginning of treatment (T0): 8 patients at CVM2 stage of growth (pre-pubertal) and 8 patients at CVM3 stage of growth (pubertal). The same criteria will be adopted for the control group.

The average duration of treatment will be 18 months. The participants will use the devices until the malocclusion is corrected. All the devices are removable, i.e. they can be taken out of the mouth.

Cephalometric analysis
For each patient included in the study, lateral radiographs will be collected both at the beginning (T0) and at the end of the treatment (T1). If the X-rays will be performed with different machines, it will be necessary to calibrate the images before starting the cephalometric tracings.
An orthodontic software (Dolphin Imaging & Management Solutions, at Patterson Technology, Verona, Italy) will be used to standardize the X-rays and perform the cephalometric tracings at

T0 and T1.
From a skeletal point of view the cephalometric values analyzed will be: SN^GoGn, SpP^GoGn, SNA, SNB, ANB, A Downs, B Downs, A:Po, Wits Index, ArGo^Gn together with the linear mandibular measurement Go:Co, Gn:Co, Gn:Go.
From the dental point of view the attention will be focused on the incisor sector level and therefore 11^SpP, 41^GoGn and 11^41.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
1. FGB (Function Generating Bite) 2. Invisalign® Mandibular Advancement Feature (MAF; Align Technology, Santa Clara, CA, USA) 3. EF Educatore Funzionale (OrthoPlus, Igny, France) 4. TWIN BLOCK (added 19/01/2023)

Primary outcome(s)
1. SN^GoGn
2. SpP^GoGn
3. SNA
4. SNB
5. ANB
6. A Downs
7. B Downs
8. A:Po
9. Wits Index
10. ArGo^Gn
11. Go:Co
12. Gn:Co
13. Gn:Go
14. 11^SpP
15. 41^GoGn
16. 11^41

All parameters will be calculated by analysing lateral radiographs taken before treatment and at the end of treatment.

Key secondary outcome(s))
Puberty stage of participant

Completion date
06/12/2023

Eligibility

Key inclusion criteria
1. Divergence between cranial base and mandibular plane within normal limits (SN^GoGn <37°)
2. Moderate crowding in the upper arch (≤4 mm)
3. Good patient compliance (18-22 h per day)

4. Excellent radiographic record quality, with adequate cephalometric point display and head rotation control
5. Aged 8-17 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
8 years

Upper age limit
17 years

Sex
All

Key exclusion criteria
1. Severe transverse dental or skeletal discrepancies
2. Severe vertical dental or skeletal discrepancies
3. Extraction treatments
4. Temporomandibular disorders (TMDs)
5. Periodontal disease

Date of first enrolment
06/07/2020

Date of final enrolment
06/07/2023

Locations

Countries of recruitment
Italy

Study participating centre
University of Turin Dental School
Via Nizza 230
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Sponsor information

Organisation
University of Turin

ROR
https://ror.org/048tbm396

Funder(s)

Funder type
University/education

Funder Name
Università degli Studi di Torino

Alternative Name(s)
University of Turin in Italy, University of Turin, Italy, Università di Torino, , University of Turin, UNITO

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Italy

Results and Publications

Individual participant data (IPD) sharing plan
Current IPD sharing statement as of 23/01/2023:
The datasets generated during and/or analysed during the current study will be stored in a publically repository (Azienda Ospedaliero-Universitaria Città della Salute e della Scienza di Torino, Torino Corso Bramante 88/90 and C.I.R. DENTAL SCHOOL. The Responsible for Data Protection or “Data Protection Officer” (“DPO”) is available at dpo@cittadellasalute.to.it). The datasets generated and/or analysed during the current study will be published as a supplement to the results publication.

Previous IPD sharing statement:
The datasets generated and/or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary

Stored in publicly available repository, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		19/03/2020	30/04/2020	No	Yes