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Manual versus sonic powered tooth brushing in patients with intellectual disability (Cepillado manual versus cepillado eléctrico para la salud oral en pacientes con discapacidad intelectual leve y moderada)

Submission date
05/07/2015

Recruitment status
No longer recruiting

Registration date
24/07/2015

Overall study status
Completed

Last Edited
16/01/2020

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Studies have shown that people with intellectual disability (ID) have higher dental plaque levels than the general population, and hence it is justified to look for methods to improve oral health in the ID population. The aim of this study is to find out whether sonic powered toothbrushes provide better clinical outcomes compared to manual tooth brushing in patients with intellectual disability.

Who can participate?
People with limit, mild or moderate ID.

What does the study involve?
Participants were randomly allocated to one of two groups. Participants in both groups were trained and supervised for the first three months in tooth brushing with a fluoride toothpaste. Participants in the test group used a sonic powered toothbrush (Sonicare®, Philips) and participants in the control group used a manual toothbrush.

What are the possible benefits and risks of participating?
Effective toothbrushing will improve dental plaque control, leading to better oral health, including prevention of gum diseases (gingivitis and periodontitis) and tooth decay. There are no risks associated with the study, except for inadequate use of the toothbrush, which can damage teeth and gums.

Where is the study run from?
Carmen Pardo-Valcarce Foundation (Spain).

When is study starting and how long is it expected to run for?
The study duration is expected to be 1 year. Recruitment lasts for about 3 months.

Who is funding the study?
ETEP Research Group (University Complutense, Madrid, Spain).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
362/2013

Study information

Scientific Title
Manual versus sonic powered tooth brushing in patients with intellectual disability: a randomised clinical trial

Study objectives
Sonic powered toothbrushes may provide better clinical outcomes when compared to manual tooth brushing in patients with intellectual disability (since this disability is manifested by diminished practical skills), when used both under supervision or in home-use, after adequate training.

Ethics approval required
Old ethics approval format

Ethics approval(s)

The regional ethical committee (CEIC Hospital Clínico San Carlos), 07/08/2013, 13/302-E

Study design
Cluster-randomised single-blinded (examiner) clinical trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Periodontal health

Interventions
Treatment groups
Monitors of the respective support groups were informed of the assignment, and trained before the study (two training sessions with the investigators, with both theoretical and hands-on sessions). The clinical evaluators were not aware of the group assignment or involved in the randomization process. Before the study, no preventive measures for oral health were provided by the monitors, and they depended on the personal private dentists of each participant.
In the test group, tooth brushing was performed with a sonic powered toothbrush (Sonicare EasyClean®, Phillips, Eindhoven, The Netherlands). In the control group, a manual toothbrush was used (Vitis Access®, Dentaid, Barcelona, Spain). When used under supervision, a 2-minute timer per monitor was used. Both groups used the same fluoride toothpaste (FluorAid 250®, Dentaid, Barcelona, Spain) and received written instructions for the use of the toothbrush, requesting not to use antiplaque agents or devices for interdental plaque control during the study. In addition, weekly questionnaires were provided to evaluate compliance, satisfaction or the presence of mechanical problems or adverse effects.

Intervention Type
Device

Primary outcome(s)
The primary outcome variable was the gingival index (Loe & Silness 1963), which was evaluated at four sites per tooth in two randomly (by coin toss) selected quadrants (one in the upper jaw, one in the lower jaw, contralateral) (Bentley & Disney 1995), by a single calibrated and trained examiner, blinded to the group allocation.

Key secondary outcome(s))
1. The plaque index (PlI) (Silness & Loe 1964) was evaluated in the same way
2. The presence of calculus (Ccl) was evaluated at the same teeth and sites, dichotomously
3. The presence of adverse effects was assessed by a visual inspection at each study visit

Completion date
30/04/2014

Eligibility

Key inclusion criteria

1. Adults from 18 to 65 years
2. Having ID (Schalock et al. 2010) categorized as limit [intelligence quotient (IQ), <70], mild (IQ 50-69), or moderate (35-49)
3. Being part of psychosocial support groups under the supervision of a trained monitor (special educators, with different university degrees in Pedagogy)

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Pregnancy or breastfeeding
2. Less than 18 teeth
3. Orthodontic treatment at the time of recruitment

Date of first enrolment
01/09/2013

Date of final enrolment
01/09/2013

Locations

Countries of recruitment
Spain

Study participating centre
Carmen Pardo-Valcarce Foundation
Monasterio de las Huelgas 15
Madrid
Spain
28049

Sponsor information

Organisation
Philips Oral Healthcare

ROR
https://ror.org/03kw6wr76

Funder(s)

Funder type
University/education

Funder Name
Universidad Complutense de Madrid

Alternative Name(s)
Complutense University of Madrid, UCM

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Spain

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2016	23/01/2019	Yes	No