

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 24/07/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 16/01/2020	Condition category Digestive System	<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Cluster randomised trial

Study setting(s)

School

Study type(s)

Prevention

Participant information sheet

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®, Dentaïd, Barcelona, Spain). When used under supervision, a 2-minute timer per monitor was used. Both groups used the same fluoride toothpaste (FluorAid 250®, Dentaïd, 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 measure

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.

Secondary outcome measures

1. The plaque index (PII) (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

Overall study start date

01/06/2013

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

60

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

Sponsor details

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United States of America

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+1 (0)800 509 7180

namtssc.helpdesk@philips.com

Sponsor type

Industry

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

Publication and dissemination plan

First report "Manual versus sonic powered tooth brushing in patients with intellectual disability: a randomised clinical trial" submitted to a journal in the field of periodontology.

Second report, in preparation, to be submitted to a journal in the field of intellectual disability.

Intention to publish date

15/07/2015

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