Can providing a fixed amount of money for dental care improve dental care for young people?

Submission date	Recruitment status	[X] Prospectively registered
27/06/2023	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
29/06/2023	Ongoing	Results
Last Edited	Condition category Oral Health	Individual participant data
17/06/2024		[] Record updated in last year

Plain English summary of protocol

Background and study aims

Dental cavities are still very common, especially among poorer populations, and this leads to unequal experiences of the disease throughout people's lives. In many countries, including the Netherlands where the PRUDENT-P4O study will take place, the problem of childhood dental cavities and the inequalities associated with it have not improved in the past ten years. The current payment system for dental care, called fee-for-service, has been criticized for hindering preventive oral care and contributing to inequalities in oral health. Alternative payment models, such as capitation payments and performance-based systems, have been suggested, but there is a lack of evidence on how effective they are for children and adolescents, especially in relation to socioeconomic risk factors. Therefore, the PRUDENT consortium has developed a new capitation payment model for two patient categories based on socioeconomic status (SES). The goal of this study to evaluate the impact of this payment model on the implementation of equity-oriented preventive oral health care.

Who can participate?

Dutch dental practices which regularly enrol and treat patients aged up to 18 years old. According to the demographic profile of the Dutch population, the patient's sex distribution will be 50% women and 50% men. The group is divided over two categories, being (A) low SES and (B) high SES in which the patient's postcode is used as proxy.

What does the study involve?

A new prevention-oriented provider payment model which aims to apply SES-risk-adjusted (low or high) capitation when remunerating dental practices in the Netherlands for their services. The amount of the capitation payment will be equivalent to current average expenditures by SES group. Capitation is paid only for registered patients with at least one check-up per year.

What are the benefits and risks of participating? Benefits:

- A significant reduction in the volume of restorative dental care
- A significant increase in the volume of preventive dental care.

- A significant reduction in the volume of invasive treatments due to caries.
- A significant reduction in the mean caries risk.
- A significant increase in access to care for patients with low SES.
- Initiates positive changes in practice organisation and care delivery (e.g. task delegation).
- Reduced treatment costs.
- Cost-effectiveness.

Risks:

- For capitation payments, concerns of "cream-skimming" have been voiced, i.e. selection by providers of those patients expected to be profitable given the system of capitation payments. If providers receive the same amount of capitation payment irrespective of the patient's treatment need, providers have a higher interest to select patients with low disease risk than patients with high disease risk. Since people with lower SES often have higher disease risks, capitation payments which do not take account of differences in disease risk could exacerbate social inequalities in access to and provision of oral care (Grytten 2017; Listl et al. 2019).

Where is the study run from? RadboudUMC (Netherlands)

When is the study starting and how long is it expected to run for? January 2023 to December 2027

Who is funding the study? European Union through Horizon Europe

Who is the main contact? Stefan Listl, stefan.listl@radboudumc.nl

Study website

https://www.prudentproject.eu/

Contact information

Type(s)

Principal Investigator

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Risk-adjusted capitation & prevention-oriented bonus payments for oral care in younger age

Acronym

PRUDENT-P40

Study objectives

Dental caries is still highly prevalent and particularly affects poorer population groups, resulting in socially unequal trajectories in disease experience throughout the life-course. In many countries worldwide, the burden of and inequalities in childhood dental caries have not declined in the past decade (Peres at al. 2019). In the Netherlands (the country where PRUDENT-P4O will be carried out), the prevalence of dental caries in younger age groups has increased within the last decade, particularly among children and adolescent with lower SES (Zorginstituut Nederland 2018).

Fee-for-service (FFS) – the currently predominant provider payment system – has been criticised as a key barrier for preventive oral care, leading to high volumes of expensive restorative care and contributing to social inequalities in oral health. Capitation payments and performance /outcome-tied provider payment systems have been proposed as potential alternatives (Watt et al. 2019). Until now, however, there is an absence of empirical evidence on SES-risk adjusted and performance- or outcome-tied provider payment models for oral care in children and adolescents.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 14/11/2023, METC Oost-Nederland (Philips van Leydenlaan 25, Nijmegen, 6525EX, Netherlands; +31 24 3613154; METCoost-en-CMO@radboudumc.nl), ref: 2023-16459

Study design

Cluster randomized controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Dental clinic

Study type(s)

Prevention, Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied

Oral health care

Interventions

Current interventions, as of 17/06/2024:

In this practice-based trial, the impact of a new prevention-oriented provider payment model will be studied which operationalizes SES-risk-adjusted (low or high) capitation to remunerate dental practices in the Netherlands for oral health care among children and adolescents. The study population consists of dental practices which regularly enrol and treat patients aged until 18 years old and will be divided in an intervention (application of the new provider payment model) and control group. The study population is divided over two categories, being (A) low SES and (B) high SES in which the patient's postcode is used as proxy. The amount of capitation payment is based on current average expenditures per SES group.

The recruitment strategy follows a two-step procedure:

- First step: dental practices will be contacted and recruited via the EU PRUDENT's network of oral health care providers in the Netherlands. Practices who indicate interest will be contacted by the study coordinators who will assess the eligibility of practices according to a checklist (inclusion/exclusion criteria). Subsequently, the eligible practice will receive a training for the study and a study material package. After this step, the dental practices are ready to enrol patients.
- Second step: after study initiation, participating dental practices will consecutively recruit patients on a rolling basis within the 12 months after study initiation. Patients are expected to be observed for up to 36 months in the study. The time from First Patient First Visit until Last Patient Last Visit is 36 months.

Previous interventions:

In this practice-based trial, the effects of a new prevention-oriented provider payment model which aims to apply SES-risk-adjusted (low or high) capitation when remunerating dental practices in the Netherlands for their services among children and adolescents will be studied. The study population consists of dental practices which regularly enrol and treat patients aged until 18 years old and will be divided in an intervention (application of the new provider payment model) and control group. The study population is divided over two categories, being (A) low SES and (B) high SES in which the patient's postcode is used as proxy. The amount of capitation payment will be equivalent to current average expenditures per SES group. Capitation is paid only for registered patients with at least one check-up in the previous 12 months.

The recruitment strategy follows a two-step procedure:

- First step: dental practices will be contacted and recruited via the EU PRUDENT's network of oral health care providers in the Netherlands. Practices who indicate interest will be contacted by the study coordinators who will assess the eligibility of practices according to a checklist (inclusion/exclusion criteria). Subsequently, the eligible practice will receive a training for the study and a study material package (including information sheets and consent forms). After this step, the dental practices are ready to enrol patients.
- Second step: after study initiation, participating dental practices will consecutively recruit patients on a rolling basis within the 12 months after study initiation. Individual patients will participate for an average of 36 months in the study. The time from First Patient First Visit until Last Patient Last Visit is 42 months. Depending on the time of enrolment, patients will participate in the study between 30 months (enrolment in the end of the 1-year recruitment period) and 42 months (enrolment in the beginning of the 1-year recruitment period).

Intervention Type

Behavioural

Primary outcome measure

Current primary outcome measure as of 17/06/2024:

Changes in utilization of oral health care according to routine data from health insurers and dental practice software after 6, 12, 24 and 36 months after study onset.

Previous primary outcome measure:

The change in volume of restorative dental care, volume of preventive dental care, volume of restorative treatments due to caries, mean caries risk and access to care for patients with low SES will be measured using routine dental electronic health record (EHR) data as delivered by the participating health care insurance companies and dental software provider after 3, 6, 12, 24, 36 and 48 months after study onset.

Secondary outcome measures

Process evaluation:

The feasibility to implement the new provider payment model, the acceptability for providers, insurers and patients and the initiated changes in practice organisation and care delivery (e.g. task delegation) will be evaluated in the beginning of the study via an online survey and, if needed, at the middle/end of the study via semi-structured interviews with relevant stakeholders such as patients/parents, dental professionals and health insurers.

Economic evaluation:

The change in treatment costs and cost-effectiveness (with focus on differences in costs vs. differences in the amount of caries-related treatments between the intervention and control groups) as a result of the new provider payment model will be analysed before and after implementation of the intervention.

Overall study start date

01/01/2023

Completion date

31/12/2027

Eligibility

Key inclusion criteria

Current inclusion criteria as of 17/06/2024:

- 1. Dental practices which regularly enrol and treat persons aged up until 18 years old.
- 2. Dental practices which use clinical management software that offers de-identified data export (in order to obtain information on caries risk)
- 3. Patients aged up until 18 years old.

Previous inclusion criteria:

- 1. Dental practices which regularly enrol and treat persons aged 4-18 years
- 2. Dental practices which use clinical management software that offers de-identified data export (in order to obtain information on caries risk)
- 3. Patients aged 4-18 years

Participant type(s)

Health professional

Age group

Adult

Lower age limit

0 Years

Upper age limit

18 Years

Sex

Both

Target number of participants

16,548

Key exclusion criteria

- 1. Dental practices which treat less than yearly 200 persons aged 4-18 years (to ensure sufficient clinical expertise and reaching the overall sample size)
- 2. Patients with disabilities
- 3. No informed consent.

Date of first enrolment

14/11/2023

Date of final enrolment

Locations

Countries of recruitment

Netherlands

Study participating centre Radboudumc

Philips van Leydenlaan 25 Nijmegen Netherlands 6525 EX

Sponsor information

Organisation

Radboud University Nijmegen Medical Centre

Sponsor details

Philips van Leydenlaan 25 Nijmegen Netherlands 6525 EX +31 24 361 4027 prudent.thk@radboudumc.nl

Sponsor type

University/education

Website

https://www.radboudumc.nl

ROR

https://ror.org/05wg1m734

Funder(s)

Funder type

Government

Funder Name

HORIZON EUROPE Health

Alternative Name(s)

Health

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

31/12/2028

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Stefan Listl (stefan.listl@radboudumc.nl)

IPD sharing plan summary

Available on request